

1 UNITED STATES DISTRICT COURT  
2 FOR THE DISTRICT OF NEW JERSEY

3  
4 IN RE: CELGENE CORPORATION,  
5 INC. SECURITIES LITIGATION. CIVIL ACTION NUMBER:  
6 2:18-cv-4772-JMV  
7 Oral Argument

8  
9 Frank R. Lautenberg Post Office and Courthouse  
10 Two Federal Square  
Newark, New Jersey 07102  
September 7, 2023

11 B E F O R E: THE HONORABLE JOHN MICHAEL VAZQUEZ,  
12 UNITED STATES DISTRICT COURT JUDGE

13 A P P E A R A N C E S:

14 CARELLA BYRNE CECCHI BRODY & AGNELLO, BY:  
15 JAMES E. CECCHI, ESQ.  
5 Becker Farm Road  
Roseland, New Jersey 07068  
and

16 BERNSTEIN LITOWITZ BERGER & GROSSMANN LLP, BY:  
17 ROBERT KRAVETZ, ESQ.  
ADAM WIERZBOWSKI, ESQ.  
18 SALVATORE J. GRAZIANO, ESQ.  
1251 Avenue of the Americas  
New York, New York 10020  
19 and

20  
21 Lisa A. Larsen, RPR, RMR, CRR, FCRR  
22 Official Court Reporter  
23 Lisa\_Larsen@njdcourts.gov  
(973) 776-7741

24 Proceedings recorded by mechanical stenography.  
25 Transcript produced by computer-aided transcription.

**A P P E A R A N C E S:** (Cont'd.)

KESSLER TOPAZ MELTZER & CHECK LLP, BY:  
ANDREW ZIVITZ, ESQ.  
MATTHEW L. MUSTOKOFF, ESQ.  
SEAN HANDLER, ESQ.  
280 King of Prussia Road  
Radnor, Pennsylvania 19087

appeared on behalf of the plaintiffs; and

GIBBONS P.C., BY:  
LAWRENCE S. LUSTBERG, ESQ.  
KATE ELIZABETH JANUKOWICZ, ESQ.  
One Gateway Center  
Newark, New Jersey 07102

and

JONES DAY, BY:  
NIDHI YADAVA, ESQ.  
RAJEEV MUTTREJA, ESQ.  
ROBERT C. MICHELETTO, ESQ.  
SARAH D. EFRONSON, ESQ.  
250 Vesey Street  
New York, New York 10281

appeared on behalf of the defendants.

1 (PROCEEDINGS held via Zoom videoconference, before  
2 the HONORABLE JOHN MICHAEL VAZQUEZ, United States  
3 District Court Judge, on September 7, 2023.)

4 THE COURT: Good morning. We're on the record in the  
5 matter of *In Re: Celgene Corporation Securities Litigation*.  
6 The civil number in this case is 18-4772.

7 Can I please have appearances, starting with plaintiff.

8 MR. CECCHI: Good morning, Your Honor. James Cecchi,  
9 Carella Byrne, on behalf of plaintiffs and the putative class.  
10 With me today are Rocky Kravetz, Adam Wierzbowski, and  
11 Sal Graziano from Bernstein Litowitz; also, Matt Mustokoff,  
12 Andy Zivitz, and Sean Handler from Kessler Topaz.

13 THE COURT: Good morning.

14 For the defense.

15 MR. LUSTBERG: Good morning, Judge. Lawrence S.  
16 Lustberg and Kate Janukowicz from Gibbons who are counsel for  
17 the defendants. With us are our friends and colleagues from  
18 Jones Day. Nina Yadava in particular will be providing oral  
19 argument today, and I'll let her introduce our colleagues from  
20 Jones Day.

21 MS. YADAVA: Good morning, Your Honor. Nina Yadava  
22 from Jones Day on behalf of the defendants. I'm joined by my  
23 colleagues here Robert Micheletto, Rajeev Muttreja, and Sarah  
24 Efronson, all from Jones Day.

25 THE COURT: Okay. Good morning, counsel.

1 By way of background, we're having oral argument on  
2 defendants' motion -- Celgene's motion for summary judgment.  
3 While the parties are aware of the standard, for purposes of  
4 the record, I want to note that a moving party is entitled to  
5 summary judgment where the movant shows that there is no  
6 genuine dispute as to any material fact and the movant is  
7 entitled to judgment as a matter of law.

8 Fact is material when it might affect the outcome of  
9 the suit under the governing law and is genuine if the  
10 evidence is such that a reasonable jury could return a verdict  
11 for the non-moving party.

12 In reviewing a motion for summary judgment, I'm not  
13 permitted to make any credibility decisions and I have to look  
14 at the evidence in the light most favorable to the non-moving  
15 party and give the non-moving party the benefit of all  
16 justifiable and reasonable inferences. As the parties know,  
17 in short, this is a sufficiency determination, not one of  
18 weighing.

19 As to the elements under section 10(b) and Rule 10b-5,  
20 the parties are in agreement, but because that's what the  
21 materiality standard will be judged against, I want to make  
22 clear that, first, defendant must make a misstatement or  
23 omission of a material fact. Whether it's false or misleading  
24 is measured by that of a reasonable investor.

25 With scienter, in connection with the purchase or sale

1 of a security upon which the plaintiff reasonably relied and  
2 that the reliance was proximate cause of plaintiffs' injury.

3 We're dealing with two different drugs at this point:  
4 the Otezla drug -- and, counsel, can you just tell me -- I  
5 want to make sure I pronounce the second drug correctly. I've  
6 read it a thousand times. I've never had to say it.

7 Is it "ozanimod"?

8 MS. YADAVA: "Ozanimod," Your Honor.

9 THE COURT: "Ozanimod." Okay. There are several  
10 statements, primarily with Ms. Curran, as to the Otezla drug  
11 and primarily Mr. Smith as to ozanimod.

12 I'm going to permit counsel to give me an introduction  
13 to their arguments. I want to give the parties the benefit of  
14 my preliminary review. Again, it's only a preliminary review.

15 As to Otezla, there certainly seems to be genuine  
16 disputes of material fact that would preclude summary judgment  
17 at this stage.

18 As to ozanimod, I think the defendants have done a good  
19 job showing that at least they should be entitled to summary  
20 judgment as to Smith's April and July statements of 2017. The  
21 November statements are not as clear to me.

22 The reason for that, so plaintiffs are prepared, is  
23 because when I did go back and review the information, it does  
24 appear that during the critical time frame, particularly going  
25 into April, Celgene had not yet identified that it was a

1 metabolite. There was concerns that it might be and what that  
2 might ensue if it is a metabolite.

3 Similarly, right before Smith's statement, all I have  
4 in front of me at this point is the e-mail that he received  
5 from Martin which did not seem to give any indication that  
6 there was going to be a problem.

7 Again, that's just my preliminary view. I can be  
8 swayed, but I figure it will help the parties direct their  
9 arguments.

10 I'll hear first from the defendant because it's their  
11 motion.

12 MS. YADAVA: Your Honor, thank you.

13 I'd like to take five to six minutes just to present my  
14 opening arguments, and I'd like to save most of my time for  
15 rebuttal to respond to plaintiff and their slides.

16 THE COURT: Absolutely.

17 MS. YADAVA: So I'll start with a brief opening.

18 Your Honor, AMF has targeted a handful of innocuous  
19 statements made by Celgene and its former officers about  
20 two different drugs, as you mentioned, and they have tried to  
21 ascribe a fraudulent intent; but after years of discovery, AMF  
22 has failed to find any evidence to support their theories, and  
23 their claims on both drugs must be dismissed for multiple  
24 reasons: falsity, scienter, and loss causation.

25 The information they provided in their slides is

1 nothing new. It is all entirely information that we have  
2 addressed in our reply brief and explained why it's  
3 irrelevant.

4 But beginning with the two remaining statements on  
5 Otezla, I understand that Your Honor is inclined to find that  
6 there may be questions of material fact here, but the truth  
7 is, when we look at all of the spaghetti that the plaintiffs  
8 have thrown up at the ceiling, none of it actually impacts the  
9 legal analysis.

10 AMF has failed to show a triable question of fact on  
11 April because when it comes to the initial inquiry to falsity,  
12 AMF has no evidence that Curran's statement of opinion that  
13 she believed net sales would rebound and why -- and remember,  
14 Your Honor, this is an opinion statement -- there's no  
15 evidence that it was false under any of the three prongs of  
16 the *Omnicare* standard.

17 All of the evidence shows that, one, she believed her  
18 statement; two, she did not embed any false facts; and, three,  
19 she did not omit material facts about her inquiry or about her  
20 knowledge that actually conflict with what she said.

21 Even if Your Honor were to find that the statements  
22 were false, which Your Honor shouldn't, with regard --

23 THE COURT: By the way, I'm not making a finding that  
24 they're false.

25 MS. YADAVA: I understand.

1 THE COURT: I'm not the jury. I'm just determining  
2 whether there's a genuine dispute of material fact.

3 MS. YADAVA: Apologies, Your Honor.

4 Even if you were to find that there was a genuine  
5 dispute about material fact about falsity, plaintiffs have no  
6 evidence that Curran intended to defraud or that she meets the  
7 high bar for recklessness in this circuit.

8 Indeed the record shows that just a few days before her  
9 statement she sought guidance and asked her colleagues whether  
10 they believed net sales would rebound and why. She simply  
11 repeated part of that information and she characterized data  
12 in charts, Your Honor, that she presented at the same time as  
13 her statements.

14 Third, on loss causation, AMF wants the Court to  
15 believe that all bad news about sales of a drug are corrective  
16 of everything positive that has ever been said about sales of  
17 that drug, but the standard for loss causation, Your Honor, is  
18 far more exacting than that.

19 And what Curran said in April are apples to the October  
20 guidance reduction's oranges. AMF fares no better on Curran's  
21 July statement for largely the same reason.

22 I'll start with loss causation because that's where we  
23 just ended on April. But Curran's July statement addresses  
24 three things: it addresses second quarter performance, market  
25 share, and prescriber adoption and says not a word about sales



1 guidance.

2           While the alleged corrective disclosure addresses sales  
3 guidance with a commentary on market growth and discount  
4 strategies, this is not loss causation. In any event, AMF  
5 cannot show falsity because it has no evidence that Curran's  
6 July statement was false or misleading, given the only parts  
7 of it that were not vague expressions of optimism were  
8 accompanied by the underlying data that it sought to  
9 characterize.

10           Just as this Court initially held with AMF's claims  
11 regarding GED 301 that were dismissed at the outset of this  
12 case, even if unduly optimistic statements -- pardon me, even  
13 unduly optimistic statements are not actionable when the  
14 underlying data itself is publicly available, and this is  
15 exactly what we have in July.

16           AMF again cannot show scienter because even if  
17 investors understood something different than what Curran  
18 intended, which AMF has no evidence of, there's no evidence in  
19 the record that Curran intended to mislead or that her conduct  
20 constituted an extreme departure from the standards of  
21 ordinary care.

22           Falsity and scienter, Your Honor, are entirely distinct  
23 prongs. Your Honor could find in our favor on either of  
24 those, finding there's no triable question of material fact on  
25 either falsity or scienter or loss causation, so all three of

1 these independent grounds lead to finding in favor of  
2 defendants.

3 AMF fares no better -- as Your Honor has initially  
4 thought, fares no better when it comes to defendants'  
5 innocuous statements about filing the ozanimod NDA or the data  
6 therein because they fail on both scienter and loss causation.

7 Your Honor, we said this in our brief and I'll say it  
8 again, but AMF offers a theory that makes absolutely no sense.  
9 They suggest that everyone at Celgene was rushing to get this  
10 product to market but at the same time they filed an NDA they  
11 knew would be rejected.

12 Of course their rejected NDA would cause delay, not  
13 expedition. In any event, AMF throws up, as it does in  
14 Otezla, a bunch of irrelevant facts which only with hindsight  
15 try to cast doubt on the NDA itself; but this case is not  
16 about whether it was a good idea to file the NDA. It is about  
17 whether Smith and Martin intentionally or recklessly misled  
18 the market by stating that Celgene would file the NDA by the  
19 end of the year, which it did, and expressing that the data  
20 from the Phase III studies was positive, which it was.

21 AMF has zero evidence of such intent. As Your Honor  
22 pointed out earlier, the record is clear that Smith and  
23 Celgene -- there's no evidence that Smith and Celgene knew  
24 there was a single major metabolite or even that Celgene knew  
25 there was a single major metabolite as of Smith's April

1 statement that she couldn't have intentionally or recklessly  
2 misled the market by projecting a year-end filing.

3 As Your Honor pointed out, Smith was informed by Martin  
4 just two days before his alleged July statement in writing  
5 about both the discovery of the metabolite, a vetted plan by  
6 former FDA consultants to address it, and an understanding  
7 that neither approvability nor timing were affected by it.  
8 There is no evidence that Smith received any information to  
9 the contrary.

10 Your Honor, when you talk about October, nothing  
11 changed. AMF does not point to a single piece of evidence  
12 sent to Smith suggesting that the plan was no longer valid or  
13 that would have given him pause to question whether the plan  
14 remained in place. That is in part because there is no  
15 evidence that it was not, which makes Martin's October  
16 statement that the Phase III data would form the basis of the  
17 NDA submission, which the team was working hard to get ready  
18 to file by the end of the year, not fraudulent as well.

19 All of the evidence in Martin's possession, just like  
20 in Smith's, suggest that the plan to address the metabolite  
21 remained on track and so did the submission. The consultants  
22 had vetted the plan; and even more, just days before Martin's  
23 statement, he asked his team to confirm that the information  
24 in the slide was accurate, which had the year-end filing by  
25 2017 and the positive Phase III data.

1 Nobody contradicted Martin's slide. Nobody said there  
2 was reason for concern. Thus, this is evidence that Martin  
3 was not reckless in his statements and did not intend to  
4 deceive. It is the only evidence about Martin's scienter.

5 Finally, AMF's attempts to hold Smith liable for  
6 corporate statements or the corporation itself liable for the  
7 statements, their imputing Smith or Martin's scienter on the  
8 corporation, find no support in the law.

9 Your Honor, plaintiff has some slides that talk about  
10 who knew what when, but these are not Smith and Martin. These  
11 are random Celgene other employees. So putting aside that  
12 Smith or Martin had no scienter to impute to anyone, there's  
13 no evidence that Smith had ultimate authority over all public  
14 statements about ozanimod.

15 Plaintiffs just don't present evidence of such  
16 authority, and that is dispositive on whether he can be held  
17 liable as the maker of Celgene's statements about ozanimod.  
18 Nor is there any precedent for applying the doctrine of  
19 corporate scienter here.

20 Where, as this Court has already held, Your Honor,  
21 these statements are not false and there's no evidence of  
22 pervasive misconduct. Your Honor held in *Schwab* that these  
23 statements are not blatantly false, they're not evidence of  
24 pervasive misconduct.

25 It's not even -- there's no evidence -- there have been

1 no rulings from the Third Circuit that corporate scienter is  
2 even a valid doctrine to begin with; but even if it is, it's  
3 used in unique circumstances and those circumstances are not  
4 present here.

5 Finally, AMF has failed to establish loss causation  
6 through the April 27th alleged corrective disclosure on  
7 ozanimod because it was both inaccurate and failed to provide  
8 any new information.

9 For all of these reasons, Your Honor, defendants should  
10 be granted summary judgment on all claims, and I'd like to  
11 reserve the rest of my time to respond to plaintiffs' counsel.

12 THE COURT: Sure. Thank you very much, counsel.

13 I'll give plaintiff an opportunity to give their  
14 opening views.

15 MR. ZIVITZ: Thank you, Your Honor. Again, Andrew  
16 Zivitz from Kessler Topaz Meltzer & Check. I'll be presenting  
17 on ozanimod. My colloquy at Bernstein Litowitz, Rocky  
18 Kravetz, will be handling Otezla.

19 Starting with ozanimod, Your Honor, what I'd like to do  
20 in light of your preliminary view is to run through April and  
21 July and October, identify just select evidence that we've  
22 amassed to date, and then briefly touch on the arguments with  
23 respect to corporate scienter and loss causation that  
24 Ms. Yadava mentioned at the end of her presentation.

25 Your Honor, we sent over some slides this morning for

1 the ozanimod slides. There's five of them and I think this  
2 will be very helpful in terms of running through what evidence  
3 we have for April, July, and October.

4 Starting with the April slide, which is the first one,  
5 here, Your Honor, on April 27th Celgene issued several  
6 misstatements and omissions in its Form 10Q, in Form 8K, in  
7 conference call slides that were posted on the company's  
8 website that focused on two things primarily: submitting the  
9 ozanimod NDA by year-end 2017 and promoting data from  
10 Phase III ozanimod studies.

11 The evidence that we have amassed shows that those  
12 statements were knowingly and recklessly misleading for  
13 failing to mention evidence, evidence of a major metabolite,  
14 that the company had at that point in time which posed a risk  
15 to the year-end 2017 NDA submission.

16 We cite to three pieces of evidence on the slide, and  
17 let me walk through them if I may.

18 First of all, on January 12th, 2017, so several months  
19 before the April 27th misrepresentations and several months  
20 after the mass balance study was completed, the ozanimod team  
21 meeting minutes circulated to Jean-Louis Saillet, who is vice  
22 president of regulatory affairs and clinical pharmacology and  
23 a direct report to Martin, and Jonathan Tran, executive  
24 director of clinical pharmacology, flagged the fact that  
25 identification of a new metabolite in the human mass balance

1 study is a risk factor and then recognized from that, if the  
2 significant new metabolite is identified, then we will have  
3 sufficient -- insufficient toxicology data to support the NDA.

4 Now, what's important here, Your Honor, is that our  
5 expert, our toxicology expert, Dr. Frederick Guengerich, a  
6 professor down in Vanderbilt, testified that at this time,  
7 January 2017, Celgene had evidence. They had evidence that,  
8 quote, there was a defect in the mass balance study which is  
9 an indication of an extra metabolite that's not been accounted  
10 for. That's in January.

11 Fast forward, Your Honor, to three days before the  
12 conference call and before the 10Q and before the 8K, a  
13 presentation was made to Saillot and to Defendant Martin  
14 stating that the data from the mass balance study indicated  
15 the existence of a new metabolite by stating, quote, it  
16 appears this new peak is real. That is evidence of a major  
17 metabolite.

18 The document went on to acknowledge, Your Honor, that  
19 Celgene might need to delay the NDA by eight months in light  
20 of that because they would have to perform additional studies  
21 on the new metabolite.

22 Another point here, Your Honor, which we lay out in our  
23 papers, is the ozanimod team's actions here are probative of  
24 scienter. They were scrambling; they were creating project  
25 teams; they were ordering studies; they were attending

1 meetings; they were reviewing data.

2 That is all indication of knowing a material fact  
3 that we respectfully submit they had a duty to disclose to  
4 investors. That's what the *Arena Pharmaceuticals* case out of  
5 the Ninth Circuit has held -- and we cite this in our own  
6 papers -- that, quote, defendants' own response to an issue  
7 contributes to an inference of scienter, and that applies  
8 here, as well.

9 I want to say something and I'm going to get back to  
10 corporate scienter at the end. We recognize that April is our  
11 toughest claim, Your Honor. I will concede that.

12 But at the same time you have Martin, who is a  
13 defendant here, who knew about the metabolite before the April  
14 statements. His scienter is imputed to the company. I will  
15 get to that in a moment, Your Honor, but let me move on to  
16 July briefly to talk about the evidence there, because at this  
17 point in time everybody knows that there is a major  
18 metabolite.

19 Here, Your Honor -- and this is on Slide No. 2 of  
20 ozanimod, these are the July 27th, 2017, misstatements and  
21 omissions, the evidence that supports falsity and scienter for  
22 them. Here again the company was promoting submitting the  
23 ozanimod NDA by year-end 2017 and, again, promoting positive  
24 ozanimod testing data.

25 But, Your Honor, just a sampling of the evidence listed



1 on Slide 2 -- and we present a whole host of additional  
2 evidence in our papers -- defendants knew by July 27th about  
3 the metabolite and Celgene would not have critical testing  
4 data before year-end when it promised that it would submit the  
5 NDA.

6 Let me again run through just the select evidence that  
7 we have on this slide. It's a continuum, Your Honor.

8 On June 6 David Wilson, the clinical bioanalytical  
9 lead, told Jonathan Tran, executive director of clinical  
10 pharmacology, that Celgene needed at least 15 months and  
11 potentially as long as three to four years to amass sufficient  
12 LTS data, long-term stability data, for relevant clinical  
13 studies characterizing the metabolite that was going to be  
14 folded into the NDA.

15 A week later Jonathan Tran takes that information and  
16 presents that information to the executive committee,  
17 including Martin and Saillot, advising them of several things.  
18 Number one, that the metabolite 273 was more potent than  
19 ozanimod; that adequate characterization of 273, including  
20 long-term stability, is, quote/unquote, required by regulatory  
21 agencies; and that the metabolite test results will not be  
22 considered validated by year-end 2017 due to a lack of  
23 long-term stability data.

24 Fast forward one month, July 17th, so we're still in  
25 advance of the July 27th misstatements by the defendants,

1 Martin is told, quote, unaddressed, the metabolite would lead  
2 to a refuse to file by the FDA and that the NDA could be  
3 delayed by one to two quarters.

4 Then you get to the final piece of evidence that we  
5 have on this slide, and this one is critical for purposes of  
6 determining scienter for -- or at least creating a genuine  
7 issue of fact for scienter as to all of the defendants. It's  
8 an internal e-mail chain circulated within Celgene that is  
9 entitled "Ozanimod Presubmission Meeting Update. Material  
10 Information. Please Do Not Share." That last part, "Material  
11 Information. Please Do Not Share" is all in caps.

12 What this document goes on to say is that the  
13 metabolite data is, quote, material information being shared  
14 on a need-to-know basis, closed quote; and importantly for our  
15 purposes it states in part that the metabolite, quote, has the  
16 potential for major implications for this submission.

17 The most important fact here, Your Honor, for purposes  
18 of scienter, the e-mail confirms that Smith, Terrie Curran,  
19 Martin, Saillot, Jay Backstrom, the chief medical officer of  
20 Celgene; Matthew Lamb, global head of regulatory affairs of  
21 I&I; Maria Palmisano, corporate vice president of clinical  
22 pharmacology; Gondi Kumar, vice president non-clinical  
23 development; and other high-ranking officials across Celgene  
24 were aware of this metabolite information.

25 Again, Your Honor, information that the e-mail called,

1 quote-unquote, material and was not to be shared outside of  
2 Celgene.

3 We respectfully submit, Your Honor, that that evidence  
4 alone raises a genuine issue of fact for the jury as to the  
5 July 27th misstatements.

6 Briefly, Your Honor, I'll move on to October, because  
7 I know the evidence becomes even more compelling. In  
8 October -- here we have statements on October 26th and  
9 October 27th in 2017. Defendants again focused on submitting  
10 the ozanimod NDA by year-end 2017 and on positive ozanimod  
11 testing data.

12 But, Your Honor, the evidence shows that the statements  
13 were knowingly misleading and incomplete for positively  
14 promoting that data and the impending NDA submission but  
15 failing to mention anything about the metabolite and again the  
16 conceded risk that it posed to the NDA.

17 Directing your attention, Your Honor, respectfully, to  
18 Slide No. 3, what I'm going to do with this slide is I'm  
19 going to work backwards. What's critical here is that what  
20 happens is on October 27th, sandwiched in between the  
21 two statements on October 26th and 28th, Celgene submits  
22 what's called a briefing book to the FDA which is a lengthy  
23 document about the impending NDA that is riddled with open  
24 questions that investors know nothing about.

25 For example, in the briefing book Celgene expressly

1 acknowledged that the NDA will, quote, not have included LTS  
2 assessments and sought the FDA's permission to submit that  
3 missing data after the NDA was submitted to the FDA.

4 But internally, Your Honor, the record shows that  
5 Celgene had conceded previously that the FDA would not  
6 consider the study results as quote/unquote validated without  
7 the data and that the FDA in March of 2017 told Celgene that  
8 it must submit full clinical study reports with the NDA.

9 Moving back to October 19th, this is a critical piece  
10 of information or evidence, Matthew Lamb sends Florence Houn,  
11 the vice president of global regulatory affairs and former NDA  
12 reviewer for the FDA, so she's familiar with NDAs submitted to  
13 the agency -- he sends her a copy of the briefing book and he  
14 warns internally, quote, I don't feel the package is ready for  
15 submission and that Celgene should wait for ozanimod NDA  
16 submission until we've completed the studies.

17 Dr. Houn agreed, cautioning she saw no legitimate  
18 rationale for the company's request to submit the missing data  
19 after the NDA review period.

20 A month earlier, September 18th, 2017, Wilson again  
21 sends Dr. Tran information, including a slide deck, confirming  
22 Celgene won't have the missing LTS data for between one and  
23 five years, depending on the study in question.

24 Finally, on August 10th, Your Honor, again moving back  
25 in time, Dr. Saillot gave a presentation at the I&I regulatory

1   affairs meeting attended by Matthew Lamb, who was head of  
2   global regulatory affairs for the company, warning that,  
3   quote, an incomplete clinical pharmacology package can  
4   potentially lead to a refuse to file.

5           Again, we respectfully submit that just this sampling  
6   of evidence, Your Honor, supports a genuine issue of fact that  
7   should go to the jury.

8           Your Honor, one point to raise here -- and let me --  
9   Ms. Yadava talked about scienter for Mr. Smith and for  
10   Mr. Martin. What's interesting here, Your Honor, is we have  
11   company statements. There's two groups of statements.

12           You have Smith and Martin's statements. There are five  
13   of those that are directly issued by them and the rest are  
14   unattributed company statements. They're in SEC filings,  
15   they're on the corporate website slides.

16           We established Celgene's scienter in two ways here.  
17   Number one, we established scienter for these statements  
18   through Defendant Smith's scienter. He was a person with  
19   ultimate authority over the corporate statements. We have  
20   evidence of that. Because of that, he acted -- because of  
21   that and the fact that he acted with scienter as the class  
22   period went on, plaintiff has established scienter for those  
23   company statements.

24           Courts have held that authority is an inherently  
25   fact-bound inquiry. We cited the *Glickenhauser* case for that

1 out of the Seventh Circuit. Closer to home there's the *Pfizer*  
2 case. The court held the testimony the top management  
3 reviewed, all of the press releases which Smith did hear, was  
4 evidence from which a jury could conclude that defendants made  
5 the statements.

6 As far as Smith's scienter, Your Honor, several points  
7 to make here. He relied on information from Mr. Martin, who  
8 knew about the metabolite on April 24th, 2017; he relied on  
9 other members of the ozanimod NDA team; therefore, Smith has  
10 scienter as well.

11 Specifically, Your Honor, moving forward into the class  
12 period, on July 27th -- I referenced that e-mail at  
13 supplemental statement of disputed facts at paragraph 105  
14 saying "Ozanimod presubmission meeting update. Material  
15 information. Please to not share," and Smith was informed of  
16 that. That document goes on to say that the metabolite,  
17 quote, has the potential for major implications to the  
18 submissions.

19 Again, Mr. Smith was informed of that information,  
20 according to that document. Smith also received the FDA's  
21 November 21st preliminary comments to the briefing book which  
22 told Celgene it needed to include the missing data in the NDA  
23 submission.

24 Mr. Smith also received a tracker memo identifying the  
25 missing information as, quote/unquote, a refuse to file issue.

1 I recognize that document was dated November 28th, 2017, but,  
2 again, it establishes Smith's mounting knowledge throughout  
3 the class period.

4 The second way, Your Honor -- and I'll finish up  
5 quickly after this. The second way in which we establish  
6 Celgene's scienter is through Martin and his team and a long  
7 list of high-ranking members within Celgene who knew about the  
8 metabolite, who knew that additional testing and delay was  
9 caused as a result of that need for additional testing.

10 Let me start, Your Honor, by saying that all of the  
11 corporate scienter cases that defendants cite to in their  
12 papers are inapposite here because they're pleading cases.  
13 The issue in those cases is whether or not the company can be  
14 deemed -- an inference can be drawn to show that the company  
15 knew about something that was being alleged.

16 Here, Your Honor, we have evidence following 18 months  
17 of discovery that more than ten high-level managers, employees  
18 within Celgene, knew about the metabolite. They knew about  
19 the risk that that metabolite caused to the NDA.

20 So because there is evidence, Your Honor, that the most  
21 senior executives in the company knew about the metabolite,  
22 they collectively chose not to disclose it and instead told  
23 the market that it was smooth sailing ahead for the NDA, the  
24 scienter of all of those individuals should be imputed to the  
25 company.

1           Second point on this, Your Honor, is that even if the  
2     pleading cases cited by defendants apply here, they still  
3     support a finding of corporate scienter. Let me explain why.

4           In *Cognizant*, Your Honor, Judge Walls stated that under  
5     any approach to corporate scienter at the summary judgment  
6     stage, to prove liability against a corporation, a plaintiff  
7     must prove that an agent of the company committed a culpable  
8     act with the requisite scienter and that the act and  
9     accompanying mental state are attributable to the corporation.

10          The *Cognizant* court then went on to explain that, if  
11     that agent either furnished information to management  
12     that is used to mislead investors or tolerated the  
13     misrepresentation after its utterance or issuance, that  
14     agent's scienter binds the company.

15          Here, Your Honor, Martin was the president of Receptos.  
16     He was the leader of the ozanimod NDA project. He thus  
17     furnished information to Celgene's senior management in  
18     Summit, New Jersey, that was disseminated in the company's  
19     statements or withheld from the company's statements as part  
20     of the quarterly disclosure process. We run through all of  
21     this in our papers, Your Honor. In addition to furnishing  
22     information, he also tolerated the misrepresentations.

23          Think about it, Your Honor. Throughout the entire  
24     class period, the company is repeatedly saying in all of its  
25     corporate documents, its form 10Qs, its Form 8Ks that are



1 going out to the market, the NDA is going to be filed at  
2 year-end '17 and the data is good. Martin let all of those  
3 statements be issued without correcting them. That is  
4 scienter that is imputed to the company.

5 At the risk of piling on, Your Honor, in addition to  
6 Martin, there's an entire core of executives here and officers  
7 who knew about the metabolite and the risks arising from it.  
8 They include: Terrie Curran, a defendant in this case, the  
9 head of I&I; Jay Backstrom, chief medical officer; Matthew  
10 Lamb, global head of regulatory affairs; Florence Houn, vice  
11 president of global regulatory affairs; Jean-Louis Saillot,  
12 who I mentioned earlier; and Jonathan Tran.

13 All of these high-level managers had responsibility for  
14 the NDA. They were not rogue employees that the corporate  
15 scienter pleading cases focus on to refuse to apply scienter  
16 to the corporate entity.

17 More to the point, Your Honor, this was a corporate  
18 decision. They made public statements about the NDA. They  
19 made public statements about the data. They did not once  
20 mention the metabolite or the risks arising from it. That is  
21 material information.

22 As -- the document that I showed Your Honor earlier,  
23 it's material information as determined by the company that we  
24 respectfully submit the jury should make a determination as to  
25 whether or not Celgene had a duty to disclose.

1           Real quickly, Your Honor, on loss causation, defendants  
2 have tried this now -- I think four times now. The statement  
3 was or the disclosure on April 29th was a Morgan Stanley  
4 report.

5           As Your Honor has held previously, this synthesized  
6 detailed information about the metabolite and reported based  
7 on that information that the timing and filing of the revised  
8 NDA would likely be between one and three years. The stock  
9 dropped in a statistically significant fashion in response to  
10 the news. Analysts tied the drop to the Morgan Stanley  
11 report. That bolsters a showing of loss causation. We cited  
12 the B of I case for that proposition. Defendants notably do  
13 not point to any other reason for the stock drop on that day.

14           Your Honor has ruled on this, as I mentioned, three  
15 times at the motion to dismiss stage, then based on  
16 evidentiary record at class certification, and later in  
17 denying defendants' motion to modify the class period.

18           Specifically, Your Honor held in denying the motion to  
19 modify -- and let me read this for the record.

20           (Reading.)

21           It appears more likely than not that the  
22 April 29th report provided the market with new  
23 corrective information about the metabolite  
24 discovery.

25           Defendants haven't provided any information, any

1 argument for Your Honor to revisit the Court's ruling. They  
2 do contend, Your Honor, that the Geoffreys report that came  
3 out several days prior somehow moves the needle here, but  
4 Your Honor rejected that argument twice, both at class  
5 certification and the motion to modify.

6 As far as defendants' last argument that somehow the  
7 Morgan Stanley report got it wrong, they contend that Celgene  
8 did not have to run certain toxicology studies and that the  
9 delay did not last one to three years.

10 It's a faulty premise, Your Honor. Celgene did have  
11 to run four non-clinical studies that the FDA relied on in  
12 approving the ultimate NDA submission and the -- or the  
13 revised NDA was not resubmitted until March 2019, two years  
14 after -- more than two years after the original submission, so  
15 there was an extensive delay.

16 Finally, Your Honor, their position misstates the law  
17 in corrective disclosures. The relevant inquiry is, quote,  
18 not what the facts reveal or not the facts revealed in the  
19 corrective disclosure but what those facts reveal to the  
20 market.

21 If the market reasonably believes that the corrective  
22 disclosure is true and the stock price reacts accordingly,  
23 that is sufficient for loss causation purposes.

24 Unless Your Honor has any questions on that front, I  
25 will yield the rest of my time and let Mr. Kravetz talk about

1 Otezla.

2 THE COURT: Before we do, let me ask, Mr. Zivitz, since  
3 we're sticking with this -- let me ask you a few questions.

4 MR. ZIVITZ: Okay.

5 THE COURT: First, what's your position as to when  
6 Celgene confirmed that there actually was a metabolite?  
7 What's your date?

8 MR. ZIVITZ: The date is -- I believe it was in June,  
9 Your Honor. As far as -- let me be clear. As far as evidence  
10 of a major metabolite -- I want to be crystal clear about  
11 this, as I mentioned with respect to April.

12 In January they see evidence of a major metabolite.  
13 Our toxicology expert, Dr. Frederick Guengerich, says at that  
14 point in time they knew they had a metabolite that was  
15 unaccounted for. As far as identifying the specific --

16 THE COURT: Fine, but your expert is not a mind reader.  
17 He can give an expert opinion, but he can't opine on somebody  
18 else's state of mind.

19 What evidence do you have that they knew it was --  
20 I know you said evidence and I've read it where they say, "If  
21 it's a metabolite, we're going to have to do the following" or  
22 "We should come up with contingency plans," but I don't have  
23 any cases that you've cited to me that they say, "There's a  
24 potential issue, let's start coming up with a contingency  
25 plan" before they've confirmed what the actual issue is.

1           Your expert may say, "That tells me it's a metabolite,"  
2 but their internal documents don't say, "We know this is a  
3 metabolite." They say, "It could be a metabolite, and if  
4 it is, this is what we're going to have to do."

5           How do I now say that is something they should have  
6 disclosed when they weren't even sure and hadn't confirmed  
7 it was a metabolite?

8           MR. ZIVITZ: Your Honor, let me address it with  
9 two points. Number one, the document from April 24th, 2017,  
10 which is a presentation that was made to Mr. Martin, stated  
11 that the data from the mass balance study indicated the  
12 existence of a new metabolite by saying it appears this new  
13 peak is real. That is scientific speak for there is a  
14 metabolite.

15           THE COURT: No, it's not, because that same document  
16 that you're referring to then goes on to say, "If it is a  
17 metabolite, this is what we're going to have to do." You  
18 can't tell me that that's scientific speak for something when  
19 they then go on to clarify and say, "If it is a metabolite,  
20 these are how we're going to have to react to it."

21           That would be -- Mr. Zivitz, I know you're plaintiffs'  
22 counsel. That would be a material omission in your argument  
23 that I would need to know, but the fact that -- I'm being  
24 facetious.

25           But the point of the matter is, their internal

1 documents say, yes, the peak is real and they wanted to  
2 confirm it was one peak, a single peak, but then it said, "But  
3 if it's a metabolite, this is how we're going to have to  
4 address it."

5 MR. ZIVITZ: Your Honor, listen, I will recognize that  
6 the case certainly grows stronger as the class period goes on.  
7 As I mentioned at the outset, April is by far our weakest  
8 point.

9 That said, Your Honor, we respectfully submit, and I  
10 think we briefed it up very well, that they had material  
11 information. All they had to say, Your Honor, was, "We intend  
12 to file the NDA by year-end 2017, but we have this data which  
13 calls that into question." That's what we respectfully submit  
14 investors had the right to know.

15 But certainly as you get to the July statement, they  
16 absolutely 100 percent knew about the metabolite. I went  
17 through the evidence, but, again, that piece of evidence right  
18 before the July 27 statements, the July 26 and 27th e-mail  
19 where Matthew Lamb is writing "Material Information. Please  
20 Do Not Share," all in caps.

21 I mean, that is securities fraud in a nutshell. The  
22 company determines it's material information and at the same  
23 time says, "We're not going to share it outside of the  
24 company," so certainly by July the company knew about the  
25 metabolite and knew that they had an obligation to disclose it

1 and opted not to.

2 THE COURT: Okay. I understand your argument as  
3 to the e-mail that this is material information, share it  
4 had on a need-to-know basis, it's confidential. I think  
5 confidentiality was mentioned twice in the e-mail chain, but  
6 my more specific question goes to defendants' argument that  
7 Smith was not aware of that.

8 I know you made a representation in your slide that  
9 Smith was aware of it, but what defendants have pointed to,  
10 it's Exhibit 122 submitted to me -- I know you used different  
11 exhibits -- but this one of the key documents defendants  
12 relied on. It's the July 25th, 2017, e-mail from Martin  
13 originally to Curran and then sent from Martin to Smith, and  
14 this is what defendants point to repeatedly saying that this  
15 is all Smith knew, not only his July statements but also in  
16 his October statements.

17 I just want to know what evidence do you have to  
18 contradict that view of defendants?

19 MR. ZIVITZ: Thank you, Your Honor. So let me walk  
20 through this step by step.

21 With respect to the July 26th and 27th e-mail from  
22 Matthew Lamb, just to reiterate, what he says in this  
23 e-mail -- again, information that was not to be shared outside  
24 of Celgene because it was material, he writes:

25 (Reading.)

1 Terri was informed yesterday evening by  
2 Philippe and I understand that Gondi Kumar, Maria  
3 Palmisano, Jay Backstrom, and Scott Smith have  
4 been informed so far. Please keep this strictly  
5 confidential for the time being.

6 He then goes on to say that this has potential for  
7 major implications for the submissions.

8 We would submit, Your Honor, that this document is a  
9 countervailing piece of evidence to the July 25th e-mail. As  
10 far as the July 25th e-mail is concerned, that document,  
11 Your Honor, is subject to different interpretations.

12 For example, the e-mail concedes that, quote -- it  
13 says it in the body of the e-mail, quote, adequate  
14 characterization of clinical pharmacology properties for  
15 RP112273, the metabolite, is required by regulatory agencies.

16 They knew that at that point in time adequate  
17 characterization required long-term stability of the  
18 metabolite and defendants didn't have it. So Smith on the one  
19 hand is being told "Don't worry, don't worry," but at the same  
20 time is being told the agencies are going to require this  
21 missing data.

22 In addition, Your Honor, it's just one piece of  
23 evidence undermined by other evidence that we have included in  
24 the record, including this Exhibit 405, which I mentioned  
25 earlier.



1 THE COURT: But I'm just focused on Smith. Part of my  
2 difficulty in reading your -- and I'll get to the other  
3 statements. I will. I'm just focused on what Smith knew and  
4 when he knew it.

5 He gets this -- it's Exhibit 122. Ultimately, the  
6 conclusion is that a lot of work remains to be done in a very  
7 short period of time in order to keep the submission on  
8 schedule.

9 He also is told that, "Our plan data should be  
10 acceptable to the agency and allow us to keep the submission  
11 on schedule."

12 So in that e-mail, before he makes his July statements,  
13 it doesn't -- there's no indication, at least when I'm reading  
14 the e-mail, saying that this is at risk now.

15 I understand what your theory is. Your theory is you  
16 should have disclosed that when you were submitting the NDA  
17 there was a potential issue. Right? I don't know the precise  
18 language, but it was an at-risk submission in light of the  
19 metabolite and the lack of corresponding study.

20 But I'm just trying to focus on what Smith knew and  
21 when he knew it. I do agree that you've given me a lot of  
22 other information about concerns that were raised in the  
23 company by other high-ranking folks at different times, but  
24 what about Smith's knowledge?

25 Outside of somebody saying, "I understand Smith knows

1 this" -- I mean, I don't know that that creates a genuine  
2 dispute of material fact unless you have deposition testimony  
3 from that person as to "What was the basis for your  
4 understanding?" and you can show a reasonable inference that  
5 Smith knew of this. I'm trying to understand what Smith knew  
6 and what you can put in Smith's mind before he makes the  
7 statements.

8 MR. ZIVITZ: Your Honor, I appreciate that. The  
9 evidence that we put forward is in our papers with respect to  
10 Smith. I mentioned the document we were just discussing. I  
11 think that the July 25th e-mail is subject to multiple  
12 interpretations.

13 Again, it includes a lot of doubt as to the -- a lot of  
14 doubt as to when the NDA will go in. I recognize that it has  
15 a representation from Martin to Smith saying that "We should  
16 be on track" or "We are on track."

17 One thing I'll note here, Your Honor, is that the  
18 July 27th statements are company statements. There's a 10Q,  
19 there are 8Ks, and Martin's scienter is imputed to Celgene for  
20 purposes of those statements because, like I said earlier, he  
21 furnished information or misinformation to the company and he  
22 let those statements go without correcting them.

23 So even if Your Honor finds that Mr. Smith doesn't have  
24 scienter for the July 27th statements, Martin and the rest of  
25 his team and multiple high-level officials within the

1 company -- as I mentioned you have Mr. Martin, Gondi Kumar,  
2 Maria Palmisano, Jay Backstrom, the chief medical officer of  
3 the company; Terri Curran, the head of I&I, all of these  
4 individuals knew. As reflected in the exhibit we were talking  
5 about earlier from July 26th and 27th, that scienter gets  
6 imputed to Celgene for purposes of Celgene's misstatements.  
7 Again, these are company misstatements.

8 THE COURT: In defendants' briefing, their motion  
9 papers focused on the actual statements that were made three  
10 times by Smith and one time Martin joined. I didn't really  
11 see them address the Qs and Ks.

12 What are you saying was represented in the Qs and Ks  
13 that was a misrepresentation?

14 MR. ZIVITZ: Your Honor, paragraph 397 of our complaint  
15 there's a statement with respect to, I believe, the NDA and  
16 the data in the form 10Q. The corporate slides were placed on  
17 the company's website, at paragraph 398 of our complaint. And  
18 at 399 additional slides are referenced there that were placed  
19 on the company website. Again at paragraph 403 of our  
20 complaint, Celgene filed a form 8K containing a press release  
21 with company statements with respect to ozanimod.

22 I apologize, Your Honor, I don't have those specific  
23 statements at my fingertips, but I will find them.

24 THE COURT: So you're saying I should look at  
25 paragraphs 397, 398, 399, and 403 of your complaint?

1 MR. ZIVITZ: Correct.

2 THE COURT: I'm going to give defendants -- I just have  
3 to have my clerk pull those specific paragraphs for me. I  
4 just want to make sure I have the right paragraphs.

5 Now I'll hear from your colleague as to Otezla.

6 MR. ZIVITZ: Thank you, Your Honor.

7 MR. KRAVETZ: Good morning, Your Honor, Robert Kravetz  
8 on behalf of plaintiffs. I'll be arguing the Otezla portion  
9 of the case.

10 Your Honor, this is a triable case as to the Otezla  
11 claims. The Court denied the defendants' motion to dismiss  
12 the April statement finding it to be an actionable opinion,  
13 and the voluminous discovery record has validated that  
14 decision, and most of the arguments advanced by defense  
15 counsel go to the weight of the evidence, not the underlying  
16 sufficiency. That's both with respect to the April statement  
17 and the new claim that -- the July statement.

18 We do have slides in connection with Otezla,  
19 Your Honor. My plan is to reference some of them, but I think  
20 I'd like to just directly address some of the comments of  
21 Ms. Yadava, starting with loss causation, because I think some  
22 of the concepts of loss causation are actually helpful when we  
23 think about falsity and scienter as well.

24 As Your Honor noted, the standard in general for  
25 summary judgment, the same standard applies to loss causation.

1 The Third Circuit has held clearly that loss causation is a  
2 fact-intensive inquiry usually reserved for the jury, and the  
3 test is whether the misrepresentation or the materialization  
4 of the risk was a substantial factor in causing the loss.

5 Under that test, a corrective disclosure need only  
6 relate to the same subject as to the misrepresentation. It  
7 need not be a mirror image, as Your Honor held in the *In Re:*  
8 *Eros* case.

9 Here the evidence shows a material issue of fact is a  
10 loss causation because the misrepresentations and omissions  
11 about Otezla sales guidance and the underlying metrics that  
12 produced that guidance related to the same subject matter as  
13 to the corrective disclosure.

14 I indicated that there's a lot of overlap in these  
15 concepts, Your Honor. It's really shown in the last  
16 three slides of the deck that we provided to the Court.

17 I think it is helpful to take a step back and just have  
18 a very brief understanding in terms of what factors were  
19 relevant to setting Otezla's budget and adjusting that budget  
20 and the public guidance through quarterly forecasts and what  
21 Celgene referred to as the latest estimates or latest  
22 assumptions.

23 Celgene began the budget process in September of the  
24 preceding year. It generally was set in December. Once set,  
25 the budget didn't change, but then each quarter Celgene would

1 provide what were known as latest estimates or latest  
2 assumptions, which would then inform any updated sales  
3 forecasts; and the underlying process and assumption that went  
4 into that process were the same.

5 Slide 9 of our presentation, Your Honor, which is the  
6 third from the end, it's just a document -- we have the  
7 citations below. These are the building blocks, Your Honor,  
8 of the budget and then the latest forecast assumptions for  
9 Celgene.

10 You can see three of the building blocks would be  
11 market size or expansion, that's the extent to which the  
12 overall market would grow; market share, the extent to which  
13 Otezla would capture shares in the market; and then market  
14 access, the extent to which Otezla could increase its access  
15 of the market typically through entering into managed care  
16 contracts to remove step edits.

17 Ultimately, these building blocks would be translated  
18 into a forecast regarding how many units of Otezla that  
19 Celgene expected to sell in a particular year, and then like  
20 all pharmacy companies, Celgene would track that  
21 contemporaneously.

22 So given how the process works -- and this is where  
23 it's related to all of the metrics, Your Honor -- Ms. Curran  
24 and the other Celgene executives would know of the impact of  
25 the failure to hit a specific metric and what that could have

1 on the forecast and the guidance.

2 We cite in our supplemental fact statement,  
3 paragraph 36, that Celgene actually scoped the amount of --  
4 quantified the degree to which market size and market share  
5 would pose a risk to the budget in the first quarter of 2017  
6 of approximately \$140 million. It got worse, and that's only  
7 with respect to two of the metrics, market share and market  
8 expansion, but it's relevant.

9 Then the next slide, because this is also addressed in  
10 the corrective disclosure, Slide 10, market share metrics were  
11 also critical to the managed-care plans and guidance. We cite  
12 in our papers that Ms. Curran actually received an e-mail in  
13 the fall of 2016 that maintaining a neutral budget upon which  
14 the guidance was built in 2017 required Celgene to drive more  
15 demand to these managed-care plans in 2017 but that conversely  
16 failing to deliver an inflection in market share would risk  
17 performing to the currently submitted budget.

18 That's exactly what happened. This is a document that  
19 shows what happened over the course of the year, but we also  
20 cited to contemporaneous information in terms of what was  
21 happening as to market share in these managed-care plans,  
22 which was consistent with what's being shown in the slides.

23 So why is that relevant to loss causation? Defendants  
24 criticize us for relying upon information unrelated to the  
25 misrepresentations, which they characterize as disconnected

1 bad news, but our brief in the statements of fact address at  
2 length the specific factors that drove the forecasting and the  
3 public guidance.

4 All of the information regarding market share, market  
5 size, market access, and inventory flow into the guidance and  
6 the corrective disclosure in this case -- and that is  
7 reflected in the next and final slide, Slide 11, Your Honor --  
8 not only touches on those subjects generally but here give  
9 specific reference to the underlying drivers of the guidance.

10 So the reduction in the guidance is attributed to  
11 overall market deceleration. It's an inability to execute the  
12 managed-care strategy, market share impact in patients  
13 previously exposed to another related drug category for  
14 psoriasis and psoriatic arthritis, and inventory fluctuation  
15 throughout the year.

16 When you compare that disclosure to the misleading  
17 statements from April and July, the misstatements clearly  
18 relate to the same subject or at minimum create a genuine  
19 issue of material fact as to whether they relate to the same  
20 subject matter. Market size, market share, managed-care  
21 execution are all essential to the guidance.

22 We cite to an e-mail Ms. Curran acknowledged that  
23 market share generally tracked market size or growth.  
24 Defendants claim that there's no relationship between the  
25 two, but Ms. Curran herself cited to a relationship in a



1 couple of e-mails we cited in our papers.

2           The managed-care strategy itself, as we just saw, was  
3 dependent upon driving inflection in market share. And all of  
4 these other metrics regarding prescriber adoption, the  
5 negative views of physicians and patients regarding Otezla,  
6 all of that impacts these particular metrics, including  
7 inventory.

8           Our brief also cites to the expert opinion of Dr. David  
9 Tabak, our expert who reviewed multiple analyst reports  
10 containing estimates for Otezla sales before and after  
11 October. These loss causation issues are typically the  
12 subject of expert testimony, which generally forecloses  
13 summary judgment, as we noted in our papers.

14           Defendants haven't challenged or even referenced the  
15 expert opinion, and that unchallenged opinion at this stage  
16 is, had the market known the truth, it would have adjusted  
17 sales estimates and projections earlier in the class period  
18 which led to price inflation.

19           So I wanted to address loss causation first because  
20 that was the particular argument that counsel seemed to take  
21 the most time addressing in the opening remarks.

22           Moving back to falsity now, with just some background  
23 in terms of how the forecasting process works, as I noted at  
24 the outset, we do have a voluminous discovery record here.  
25 The Otezla claim is a highly fact-intensive claim, and at

1 minimum there's a material dispute of fact as to whether  
2 Ms. Curran sincerely believed the April statement when she  
3 made it. And, as I noted, most of the arguments here go to  
4 the weight and not the sufficiency of the evidence.

5 Defendants didn't address the April statements  
6 directly. Ms. Yadava did not address those statements  
7 directly in her opening remarks. I would incorporate by  
8 reference our briefing and our slides in this matter,  
9 Your Honor -- it's Slides 2, 3, and 4 -- and absent specific  
10 questions, I'll move on to the additional -- address the  
11 additional arguments that counsel made.

12 THE COURT: Let me ask you, just so I understand your  
13 arguments. It didn't seem to me as though you were looking to  
14 say her opinion that it was exceptionally strong in the first  
15 statement that she made during the first quarter earnings call  
16 in response to an inquiry by a UBS analyst, but then you  
17 pointed to certain things that she did say that have a factual  
18 basis. I know that one of the arguments you had is that she  
19 said, "If you look at market share, we continue to grow market  
20 share."

21 I'll direct this to defense counsel, but I have seen  
22 the internal e-mails, including her e-mail saying, "We look  
23 flat," so I'll direct that to defense counsel.

24 Tell me your theory about the minimal drawdown. By way  
25 of background, both parties seem to agree that because of the

1 price increase coming in 2017, that I'm guessing the  
2 wholesalers built up their inventory in the fourth quarter of  
3 2016. I guess I have a couple questions.

4 One, it doesn't seem as though anybody was surprised  
5 about the build-up of that inventory because of the price  
6 change, so what's your argument when she said, "We saw minimal  
7 drawdown on inventory"? I just want to understand that a  
8 little bit better.

9 MR. KRAVETZ: Certainly, Your Honor. So it is our  
10 argument that it's misleading to say that there was a minimal  
11 drawdown in inventory. Whether that's viewed as an embedded  
12 false statement of fact or whether it's in prong three in  
13 terms of omission liability, there's some overlap between the  
14 various categories.

15 What we have here is we have an inventory starting  
16 point in the first quarter that was 20 days on hand. The  
17 record shows that was well above the normal range of 10 or  
18 13 days on hand. We cite to that on our papers.

19 So by the end of the quarter, that metric decreases  
20 from 20 days on hand down to 13, which is within the normal  
21 range. It's our position that's not minimal or modest, as  
22 characterized by the defendants, particularly given the  
23 internal documents we have showing that inventory adjustment  
24 to get to that normal range was one of the key factors that  
25 was driving the first quarter weakness. We also have

1 testimony from Ms. Curran that she was aware that there were  
2 discussions of a significant inventory drawdown, which is  
3 different than how it was characterized.

4 Defendants point to the fact that later in that April  
5 call that Celgene and Ms. Curran actually quantifies the  
6 inventory adjustment as 35 to \$40 million, I believe, but  
7 that's really of no moment because the numbers there don't  
8 necessarily say anything about the relationship between the  
9 inventory and the company's forecast.

10 Ms. Curran herself said that that number was at the low  
11 end of the range, so nothing contextually to an investor as to  
12 whether that number is minimal or not is of no help to a  
13 reasonable investor.

14 I'd also note, Your Honor, we cite on our supplemental  
15 statement of fact 36 to Plaintiffs' Exhibit 36 and that's a  
16 March 24th document in which Celgene indicated that it had a  
17 change in inventory assumption as a result of the first  
18 quarter drawdown, an assumption that went into the budget.  
19 That's at page 367, for the record.

20 But we also allege that the inventory portion of the  
21 statement as a whole is misleading because Celgene itself drew  
22 a direct connection between inventory and demand. By  
23 reference, we allege this in our complaint, paragraphs 143,  
24 144, and 146; but we show in our papers that there are these  
25 internal communications where demand was driving sales

1 weaknesses and forecast shortfalls, and that lack of demand  
2 would be critically important to an investor assessing the  
3 ability of the company to attain its sales guidance.

4           So whether the inventory metric is viewed under the  
5 second prong of *Omnicare* as being an embedded false statement  
6 or the third because it's not telling the whole truth about  
7 how bad things actually were in driving demand and the company  
8 itself later in the corrective disclosure attributes inventory  
9 fluctuation throughout the course of 2017 as one of the  
10 material reasons why it didn't meet its budget, we think that  
11 we've educed sufficient facts at this stage with respect to  
12 that portion of the claim.

13           THE COURT: Okay.

14           MR. KRAVETZ: Your Honor, Ms. Yadava mentioned the  
15 puffery and vagueness. I would just note the Court already  
16 ruled that the April statement was not vague or did not  
17 constitute puffery.

18           The April statement referred to the key drivers to the  
19 company's performance and referenced that the underlying  
20 dynamics of the business were exceptionally strong. On  
21 page 34 of Your Honor's motion to dismiss opinion, Your Honor  
22 rejected the vagueness and puffery challenges.

23           The arguments in our brief are consistent with the  
24 Court's prior opinion. These are not just vague and  
25 non-specific expressions of corporate optimism but a

1 mischaracterization and/or omission of specific metrics in  
2 particular subjects and certainly not a basis at summary  
3 judgment for a decision related to puffery or vagueness.

4 Defendants make the same argument with respect to the  
5 July statement. I'll just move on to the July statement in  
6 terms of the portion of that statement relating to the key  
7 performance indicators.

8 Again, this isn't just a vague expression of optimism  
9 like, "I feel really great about the quarter" or "I'm just  
10 really excited about sales projections."

11 As with the April statement, the defendants are touting  
12 the strength of key performance indicators. They specifically  
13 reference to market share and prescriber adoption. There's no  
14 difference between the two statements, the April and July  
15 statement, from a legal standpoint and no basis to assert that  
16 the July statement should be treated any differently from a  
17 vagueness or puffery standpoint. The jury must assess the  
18 statement as a whole collectively.

19 Just finally, Your Honor, I think the last direct  
20 argument that defense counsel made with respect to the July  
21 statement relates to the statement about market share.

22 Now, the principal argument that defendants advanced  
23 was that Ms. Curran was referring to a chart showing that  
24 market share grew over a 30-month period so the statement was  
25 in fact accurate. There seems to be a concession now that the

1 statement is related to the second quarter, not to the  
2 preceding 30-month period. But I'll note on Slide 6 we  
3 actually walk through the evidence as to how Ms. Curran had  
4 conflicting information relating to market share in the second  
5 quarter of 2007 [sic] in terms of slides that she received,  
6 her own e-mails characterizing market share, her deposition  
7 testimony, and the fact that she received access to other  
8 information showing additional market share indicators as  
9 declining.

10 So, you know, now it seems to be more of a 180, and the  
11 argument now is that the July market statement -- I think the  
12 argument is it's immaterial because a reasonable investor  
13 should have known that the statement was inaccurate if limited  
14 to the second quarter of 2017.

15 Again, this is a question of materiality for the jury.  
16 The defendants don't point to any evidence from an analyst  
17 or any public reporting showing the import of any prior  
18 disclosures regarding market share. There's not any citation  
19 to an analyst who said, "Ah-hah, Celgene made a mistake" or "I  
20 think they misrepresented something."

21 So, regardless, asking a reasonable investor to take  
22 away a contrary conclusion about market share from a slide  
23 that defendant concedes in her deposition that she did not  
24 even reference about market growth driving pickup of U.S.  
25 Otezla sales which doesn't otherwise contain any percentages

1 for the prior quarters appears to show an uptick at the end of  
2 the second quarter. That's insufficient at this stage.  
3 That's an argument that goes to the weight, not the  
4 sufficiency.

5 And I would just note, in conclusion, on the falsity  
6 point we did include citations in our papers, supplemental  
7 statement of fact 63 in our response to the statement of facts  
8 82, in which Ms. Curran wrote in an e-mail in September, just  
9 a month and a half later, where she specifically characterized  
10 overall national market share running flat versus increased  
11 forecasting -- forecasted in 2017.

12 Finally, just one minute on scienter, Your Honor.  
13 Defendants don't spend much time in their briefing on  
14 scienter, other than referencing the standard in claiming that  
15 it's a high bar to meet.

16 The Third Circuit has consistently held that plaintiffs  
17 may establish scienter upon evidence that a defendant knew  
18 facts or had access to information suggesting that their  
19 public statements were not accurate, and that is, if you paint  
20 a far rosier picture or offer incomplete or misleading  
21 information implying that the insider knowledge was different  
22 from what the public was hearing.

23 That's why there is significant overlap between the  
24 falsity evidence when you're talking about opinion-based  
25 liability in scienter but certainly -- and we have noted on



1 Slides 7 and 10, we have set forth all of the evidence  
2 relating to scienter. Certainly scienter is a triable issue  
3 at this stage, given the information Ms. Curran knew and what  
4 she said behind closed doors but did not disclose publicly.

5 Unless Your Honor has any further questions, I'll  
6 conclude my remarks.

7 THE COURT: Just one question before I turn it back  
8 over to defense counsel. I have the disclosure, by the way,  
9 in front of me. I believe it's Exhibit 86.

10 You contend this is an October 2017 corrective  
11 disclosure, and you show what it was attributed to. Let me  
12 just ask you your overall view as to what it was attributed  
13 to: overall market deceleration, inability to execute  
14 managed-care strategy, market share impact in patients  
15 previously exposed to biologics, and inventory fluctuation.

16 Just so I understand, you're saying none of this was  
17 new information that they received after the second quarter  
18 going into the third quarter. That this was information, if  
19 properly analyzed, would have shown the direction of Otezla's  
20 sales vis-à-vis the forecast.

21 MR. KRAVETZ: Yes, Your Honor. At the time of the  
22 first quarter and of the second quarter, this is information  
23 that was known to Ms. Curran and other executives that  
24 concealed known risk, that the risk only materializes in  
25 connection with the corrective disclosure in October; and,

1 certainly, information that had it been known at the time  
2 would have had an impact on the price of the stock given that  
3 once all of this came -- what was known to the market and  
4 defendants downgraded the public guidance consistent with the  
5 information that they knew going back to the first and second  
6 quarter, you had a significant price drop.

7 THE COURT: The guidance was the change of  
8 approximately 250 million, and that was the only drug whose  
9 2017 guidance was changed?

10 MR. KRAVETZ: That's correct, Your Honor.

11 THE COURT: Thank you. That's all I have for you.  
12 I'll turn it back over to your adversary.

13 MR. ZIVITZ: Your Honor, it's Andrew Zivitz. I  
14 apologize. Can I make one more point on ozanimod since we  
15 were talking so long about scienter? There was a piece of  
16 evidence that I neglected to mention that I think is  
17 important.

18 THE COURT: Sure.

19 MR. ZIVITZ: Your Honor, in terms of Smith's scienter  
20 and the company's scienter, the one document that I neglected  
21 to mention, there was a May 16th, 2017, e-mail that  
22 Dr. Saillot sends to Martin imploring him to inform  
23 Defendant Smith about the metabolite.

24 He goes on to say that there are risks from the mass  
25 balance study, and he says that the December filing date is in

1 jeopardy and a best-case scenario and he recognizes that this  
2 discovery is, quote-unquote, painful and bad news. Martin  
3 responds saying, "We'll talk about it."

4         The reason why I'm raising this, Your Honor, is whether  
5 Martin told him or not, if he chose to hold back the  
6 information, Martin's scienter, it's misinformation that is  
7 being sent to the company. It imputes scienter for purposes  
8 of Celgene's scienter as of the July statements.

9         So even if Smith did not know at that point in time,  
10 even if the only informing that Smith received was that e-mail  
11 from Martin -- and I think the other document we were talking  
12 about earlier, Exhibit 223 calls that into question -- this is  
13 misinformation that as the *Cognizant* courts recognized at the  
14 pleading stage, it's the furnishing of misinformation that  
15 imputes scienter to Celgene for purposes of the July 27th  
16 misstatements.

17         Thank you for indulging me there, Your Honor.

18         THE COURT: You're welcome.

19         MS. YADAVA: Thank you. I'll start with ozanimod, and  
20 I'll just start with the point that Mr. Zivitz just made.

21         That e-mail was, as plaintiff conceded earlier, before  
22 the metabolite was identified. Even plaintiffs' counsel  
23 itself said today that the metabolite was not identified with  
24 any certainty until June of that year, the May 16th e-mail has  
25 no relevance to scienter.

1           Additionally, Your Honor has covered some of the points  
2           that I wanted to make about April. It's clear that there is  
3           no metabolite as of April.

4           I just want to point out something that I think -- I'm  
5           going to walk through plaintiffs' slide because I think this  
6           is their best evidence and I can tell you exactly why it's  
7           irrelevant to the --

8           THE COURT: You're going to use their slides?

9           MS. YADAVA: Yes.

10          THE COURT: Just let me know what slide you're on. I  
11          have it.

12          MS. YADAVA: I'm just starting with 1 of the scienter  
13          evidence for April. These are what I believe Mr. Zivitz was  
14          walking through, and I just want to walk through and explain  
15          why they're irrelevant.

16          I want to point out that what plaintiff has done  
17          throughout this case is try to create issues of material facts  
18          by just giving us one sentence or one line from an e-mail  
19          without giving us the rest. That is, I would submit,  
20          disingenuous.

21          If you look at the January 2017 point from  
22          Dr. Guengerich that Your Honor explained, this expert opinion  
23          does not change the facts, this does not create a genuine  
24          issue of material facts. But when plaintiff cites this, it  
25          says there's an indication of an extra metabolite that's not

1 been accounted for, right, there's evidence that there was an  
2 indication.

3 But Dr. Guengerich says just a few lines later it was  
4 not possible to determine from the study's preliminary results  
5 whether the data indicated a single metabolite or something  
6 else.

7 So this is what happens throughout the slides,  
8 throughout the facts, facts that are presented. They're not  
9 the entirety of the fact. We cannot create an issue of fact  
10 by presenting half a fact. That doesn't work to defeat  
11 summary judgment.

12 Same thing when we talk about the -- plaintiffs'  
13 focused a lot on this --

14 THE COURT: All right. So I'll apply the 10(b)  
15 standard here to oral argument, too. If you're going to make  
16 a statement, it's got to be a full statement and no material  
17 omissions. Okay?

18 MS. YADAVA: Okay, Your Honor. That I can do.

19 THE COURT: Okay. I'll do it across the board. Use  
20 the 10(b) standard when you're arguing before this Court.

21 Go ahead.

22 MS. YADAVA: I think we've done that, Your Honor. We  
23 have tried to put in the rest of the facts that are missing or  
24 omitted from plaintiffs' arguments in our reply brief, but I'm  
25 just going to emphasize a few.

1           Your Honor noted that all of the information on the  
2 slide says, you know, it appears this new peak is real, if the  
3 significant new metabolite is identified, it's all contingency  
4 planning. It does not address that any metabolite was found.  
5 Your Honor has already accepted that.

6           But when we talk about Smith's scienter for any of the  
7 statements, nothing changes. Smith received an e-mail from  
8 Martin on July 25th, Your Honor pointed it out, in which he  
9 says approvability is not -- approvability and timelines are  
10 not affected by the metabolite.

11           This is after Celgene had hired outside former FDA  
12 officials to come in and look at their strategy, to opine on  
13 what they intended to do as their intended plan as to how to  
14 address the metabolite and determined that their plan was  
15 going to work. Right? They put in place a plan, and there's  
16 nothing to suggest the plan ever fell off track.

17           Mr. Zivitz focused a lot on what Backstrom knew and  
18 what Lamb knew and all of these other people at the company,  
19 but this is not how corporate scienter works. You can't just  
20 take a little bit of one person's scienter and impute them all  
21 in the company.

22           As I said in my opening, corporate scienter should not  
23 even apply here. These are not the facts that rise to  
24 corporate scienter. When you look at the precedent in the  
25 circuit and you look at cases of *City of Roseville* where there

1 was a price-fixing conspiracy -- and even then the courts said  
2 these are not the egregious circumstances where corporate  
3 scienter should apply.

4       If plaintiffs wanted to say there was pervasive  
5 misconduct and all of the employees' scienter should be  
6 bundled together and imputed on the company, they should have  
7 had evidence to support that. There's no evidence that  
8 everybody at the company got together, talked about the  
9 metabolite, discussed it in detail, and then decided "In any  
10 event, we're going to keep going forward, we're going to lie  
11 to the market about it, we're going to all each independently  
12 approve the submission." Where is the evidence of any of  
13 that? There is none.

14       This is not a situation for corporate scienter because  
15 there are no blatantly false statements. "We intend to file  
16 the submission by year-end" or "We are going to file our  
17 submission by year-end," those are not blatantly false.

18       Your Honor held that on the very favorable to plaintiff  
19 standard at the motion to dismiss we're going to move forward  
20 in this case because it could be potentially misleading, but  
21 never did Your Honor hold those statements were blatantly  
22 false because it can't be and they're not.

23       This is not a situation where corporate scienter should  
24 apply at all. In their papers --

25       THE COURT: I don't understand plaintiff to be arguing

1 that. What I understand plaintiff to be arguing -- we can  
2 discuss when the knowledge should be imputed or who had  
3 knowledge at what time, but I think what plaintiff is saying  
4 is at a certain point there were -- folks who were directly  
5 involved in the project realized that this was an at-risk  
6 submission. Some said it would be okay; others said no. We  
7 know with the benefit of hindsight it was an at-risk  
8 submission. You got the RTF.

9 I think the concern is when you're telling the public  
10 "We're submitting by year-end," but internally you know this  
11 may not go through, you have a duty to disclose that to the  
12 investing public so they realize that there is an issue, the  
13 FDA may not accept this submission. "We don't have the  
14 long-term study on the metabolite" -- which is what the FDA  
15 requires -- "although we're going to see if the FDA will give  
16 us an exception here."

17 I think that's the issue, as far as I understand it.

18 MS. YADAVA: Your Honor, that's not quite what  
19 plaintiffs argue in their papers. They say that the scienter  
20 of Smith and Martin should be imputed to the company, to begin  
21 with, and Smith and Martin do not have scienter.

22 THE COURT: Martin is different than Smith. You've  
23 argued Smith strongly. Martin seems to be very well aware of  
24 the concerns with the FDA submission.

25 MS. YADAVA: Maybe I can talk about Martin then,



1 Your Honor, because I think -- I feel just as strongly that  
2 Martin did not have scienter and I haven't addressed that yet.

3 Martin's only evidence -- the only evidence of Martin's  
4 scienter is the contemporaneous e-mail he wrote in July where  
5 he says that approvability is not affected by the metabolite  
6 and neither is timing.

7 That is the only evidence we have of his actual  
8 scienter. Moreover, plaintiffs just completely ignore the  
9 entire process by which they hired outside experts, outside  
10 experts weighed in on the submission.

11 There's a slide presented to the experts that clearly  
12 says there's no long-term stability data that we will have at  
13 the time of filing. Nobody said they would give an RTF.

14 We're not weighing evidence. This is the only evidence  
15 of Martin's mental state. He --

16 THE COURT: There plaintiffs say that when you actually  
17 deposed the FDA consultants they said, "We weren't really  
18 asked about the long-term stability."

19 You might have thrown a slide at them and said, "By the  
20 way, they passed off on it." And when they were deposed, they  
21 said, "No one really focused on that issue for us." So you're  
22 kind of like trying to say, "We showed them a slide, they  
23 didn't raise an objection, so everybody thought it was  
24 going to be okay."

25 MS. YADAVA: Your Honor, they did not quite say that.

1 They said they don't remember --

2 THE COURT: I'm paraphrasing. I don't have the  
3 transcript in front of me.

4 MS. YADAVA: Right. I'm just trying to explain that  
5 these experts were deposed years later. They could not  
6 remember a specific discussion of the long-term stability, but  
7 they do remember being shown the slides, and all of them  
8 testified that they did not believe the company would get an  
9 RTF.

10 They were shown the slides, they testified to such, and  
11 they said that they did not believe the company would get an  
12 RTF. We have multiple consultants who will point that out --  
13 we'll point that out where the testimony says that, but each  
14 of the consultants had said very clearly that there was no  
15 RTF.

16 Here it is. I'm sorry. I've got colleagues on the  
17 side here.

18 THE COURT: That's okay. It's a lot of information. I  
19 understand they're helping out.

20 MS. YADAVA: By the way, they're also contemporaneous  
21 e-mails at the time which would have been bizarre, right, for  
22 Martin to write e-mails saying things like recent feedback  
23 from ex-FDA reviewers, which he says in the same e-mail,  
24 Your Honor, that you just pointed out, tox, clin, and pharmacy  
25 division director level:

1 (Reading.)

2 Recent feedback from our ex-FDA reviewers  
3 indicates that our plan data should be acceptable  
4 to the agency and allow us to keep the submission  
5 on schedule."

6 And Lesko specifically testified in his deposition  
7 that, no, he had strong efficacy data and he did not think  
8 that they would get an RTF. Jacobson-Kram said he didn't tell  
9 Celgene at any point he thought they would get an RTF. None  
10 of these consultants testified there would be an RTF, and this  
11 is the strongest -- this, coupled with Martin's  
12 contemporaneous review of the evidence, shows Martin did not  
13 have scienter either.

14 THE COURT: What about the July 26 going into 27th  
15 e-mail chain, the "This is material information, it's  
16 need-to-know" and there's internal concerns being raised about  
17 how this metabolite is going to play out?

18 They said they discussed it with Martin: "Jean-Louis  
19 has already had a brief discussion with you about this."

20 Whatever the experts may say, you have other people who  
21 are dealing with the project internally pointing out that this  
22 could be a real issue.

23 MS. YADAVA: They're not saying it could be a real  
24 issue, Your Honor. I have the e-mail in front of me. All  
25 they're saying is that --

1           THE COURT: Don't even try it. You're going to lose  
2 your credibility if you try to tell me it's not a real issue.  
3 You can explain it, but when somebody says to flag this as  
4 material information being shared on a need-to-know basis,  
5 you're going to have a tough argument telling me that's not  
6 really what it means.

7           MS. YADAVA: Your Honor, I'm not trying to tell you  
8 what it means. I'm just trying to explain what the rest of  
9 the e-mail explains.

10           Number one, when it says "material information," it's  
11 not being sent -- it's not material in the sense of securities  
12 fraud. Right? Your Honor --

13           THE COURT: You can argue that to the jury, okay, what  
14 the definition of materiality is. Let's just agree it's  
15 important, but go ahead.

16           MS. YADAVA: Yes. So there's nothing in this e-mail  
17 that I see that suggests that they're going to get an RTF.  
18 All they're saying is that they discovered a metabolite, they  
19 don't want to share this widely because they don't know --  
20 they just don't want to share it widely. There may be a  
21 number of reasons not to share it widely, but we know the  
22 discovery of the metabolite was not hidden internally within  
23 Celgene.

24           Lots of people knew about it, lots of people discussed  
25 it. It would be imprudent for a pharmaceutical company to

1 discover a metabolite and not discuss what its potential  
2 ramifications, inclinations could be --

3 THE COURT: They didn't discuss it publicly. That's  
4 the issue here.

5 MS. YADAVA: No, but they discussed it internally,  
6 Your Honor, and determined --

7 THE COURT: Doesn't that show that have an issue "We're  
8 not discussing it publically" when you're saying this is  
9 important information? Doesn't that kind of prove the  
10 plaintiffs' point that you acknowledge this is important, "we  
11 have to discuss it, we don't know how it it's going to play  
12 out"?

13 So you're saying, "It's important for us to discuss it  
14 internally, but we didn't have to disclose it."

15 MS. YADAVA: Your Honor, I think there's actually a  
16 number of instances of that. Not all important information  
17 must be shared with the market. If it's important to the  
18 company but there's a plan to address it, a plan that has been  
19 blessed, expressed to consultants and there is no evidence to  
20 the contrary -- all of the cases that the plaintiff point to  
21 about saying one thing to the market and having other internal  
22 information about it, it all included having feedback from the  
23 FDA that that plan was not acceptable.

24 We have no feedback from the FDA at this juncture,  
25 Your Honor. It's simply a situation where they have

1 discovered a metabolite and they have a plan to address it.  
2 These documents do not contradict or pass doubt on whether  
3 there's a plan in place to address it. No one is down-playing  
4 that the metabolite was discovered by this juncture, by  
5 July 27th, but if there's a plan in place to address it,  
6 there's no reason for Celgene to tell the market unless they  
7 believe it affected their submission materially.

8 THE COURT: So you tell me there was a plan in place to  
9 address it when, after the FDA consultants, according to --  
10 who have already blessed it, we have Matthew Lamb internally  
11 saying, "Next steps are unclear to me at this moment. As  
12 Amaryllis notes, the team in San Diego seems to be most  
13 concerned with having to repeat clin pharm studies such as  
14 DDI," et cetera.

15 So even after the consultants said, "Don't worry  
16 about it," you have internal folks at the company saying, "We  
17 don't know how we're going to go forward. We're going to push  
18 off the FDA meeting for the time being, and there's a concern  
19 we may have to repeat the clinical pharm studies which, by the  
20 way, FDA guidance basically said, 'You're going to need your  
21 long-term studies.'"

22 So you have FDA guidance telling you what you need.  
23 Put aside the FDA consultants. No offense to consultants but  
24 I found if you pay somebody enough money they're going to give  
25 you whatever opinion you want, so I'm always a little bit

1   dubious of that type of information.

2           But internally the people whose necks are on the line  
3   with this submission -- because the FDA consultants don't have  
4   any skin in this game, the people whose necks are on the line  
5   are saying, "Look, this is a concern." Right? We know FDA  
6   says we need long-term studies. We know that. We know when  
7   you make your submission you ask for an exception to the FDA  
8   to rule in the briefing book.

9           How can you now say, "Well, we had a plan to address  
10   it" when everybody said, "We know it's not what the FDA  
11   requires and we're going to ask for an exception when we do  
12   our briefing book to the FDA"? And the FDA said, "We're not  
13   giving you the exception," ultimately.

14           I'm lost when you say, "This was not an issue, we had a  
15   plan." Yes, but it was a bad plan. And you had people saying  
16   it may not work, and critically FDA -- you knew the FDA  
17   required this for a metabolite and you were going to ask for  
18   an exception to what the FDA wanted.

19           MS. YADAVA: Your Honor, I just have to respectfully  
20   disagree. I don't think the FDA said no in November, but  
21   coming back to Your Honor's points, this is Matthew Lamb's  
22   opinion in an e-mail. It is not Martin's opinion, it is not  
23   Smith's opinion.

24           Only -- Martin and Smith are the only speakers at this  
25   time. They are the only ones who are speaking. We could

1 debate for hours what these documents mean and what I think  
2 they mean and what you think they mean, but, Your Honor,  
3 Matthew Lamb didn't make public statements to the market. His  
4 scienter -- even if he believes that there's an issue here,  
5 his scienter does not matter.

6 THE COURT: No, but the issue is that Martin is the one  
7 in charge of this. You tried to -- even though he's the  
8 president and COO, you've tried to -- I know it's crazy, these  
9 corporate arguments drive me crazy because the highest person  
10 always has the least amount of information, according to their  
11 attorneys.

12 Let's say I accept that for a moment, that the person  
13 running the ship really doesn't know what's going on because  
14 they're not given the material information they need to make a  
15 correct public statement. That's basically the argument. I  
16 find it frustrating, but that's the argument.

17 Let's look at Martin. Martin is in charge of this  
18 project.

19 MS. YADAVA: Right.

20 THE COURT: Now you're saying, okay -- his team members  
21 are saying, "We don't know if this is going to work." You're  
22 saying, "Well, you can't attribute that to Martin. They kept  
23 it quiet from the top guy."

24 Maybe they did, sometimes people do that. But I don't  
25 know how you can say Martin, when he made the statements in



1 October, shouldn't have said, "By the way, there's a risk that  
2 this may not go through because we have a metabolite" -- I  
3 don't know how he could phrase it. He could probably do --  
4 I know there's a bunch of euphemisms for that, I don't know  
5 how you do it, but corporate speak for like "We have a  
6 problem," which usually doesn't sound like a problem but at  
7 least when attorneys get ahold of it you say, "Well, it  
8 disclosed the problem."

9           So what do I do with the fact that you are raising  
10 these internal concerns? Martin is in charge of it, and it  
11 certainly seems as though there was critical mass, no pun  
12 intended, saying that this may not go, regardless of what the  
13 FDA consultants say.

14           MS. YADAVA: Your Honor, there are always stark  
15 differences of opinion but they do not reveal scienter.  
16 Different people on a team can have different views. That  
17 does not mean that Martin's was reckless or Martin did not  
18 honestly believe the statements he made.

19           THE COURT: You're right, but I'm not determining that.  
20 I'm determining whether a jury will decide that. That's what  
21 I have to determine.

22           MS. YADAVA: Your Honor, plaintiffs have to present  
23 some evidence that reflect on Martin's scienter. This e-mail  
24 can't possibly reflect on Martin's scienter. It wasn't sent  
25 to Martin.

1           This is the problem with all of plaintiffs' evidence.  
2 They keep conflating speakers and people in different roles.  
3 If you look at their slide on --

4           THE COURT: They do it but you do the same thing. You  
5 take the highest person in charge of everything and you say  
6 they didn't know anything, and I'm like, "Okay." At a certain  
7 point, there's a reasonable inference that the person in  
8 charge of the project knows what the concerns are being raised  
9 in the project.

10           I mean, to me, that's just -- if I'm running my  
11 chambers and I'm working on opinions with my law clerks,  
12 there's a reasonable inference I know what my law clerks are  
13 working on. But you try to say, "Well, okay, important  
14 members of the team were raising like, 'This may not go  
15 through, we may have to do the testing,'" and then you say,  
16 "But he didn't have any idea of those discussions." It's  
17 silly.

18           MS. YADAVA: Your Honor, I don't think it's silly. I  
19 think different people can have different views, and the idea  
20 is these are discussed, the different concepts of what the  
21 company should do in response to the metabolite.

22           They all -- even those people, Matthew Lamb and all,  
23 signed off on the NDA, so eventually they became comfortable  
24 that they had enough information to submit an NDA. Or  
25 everybody at every level is in cahoots to submit this NDA they

1 know is going to get rejected.

2 THE COURT: Counsel, I know you keep arguing that, but  
3 you didn't hear what plaintiff said and you didn't hear what I  
4 said. Nobody is saying they knew for certain.

5 The question is did they know it was at risk when they  
6 put it in and they were hoping that the FDA was going to not  
7 follow through with their normal FDA procedures in this.  
8 That's what needs to be disclosed.

9 If you're going to submit to a federal regulatory  
10 agency and you know this is what they require and you're  
11 asking them to have an exception, does that need to be  
12 disclosed? That's what the question is. It was at risk  
13 and --

14 MS. YADAVA: Your Honor -- I'm sorry.

15 THE COURT: I don't disagree. If they knew it was  
16 dead, it didn't make any sense. But the question is did they  
17 know there was a potential it was going to be kicked back?

18 MS. YADAVA: Your Honor, under the case law there needs  
19 to be a substantial likelihood that they actually believed the  
20 submission was not going to be accepted. They don't have to  
21 take a pessimistic view.

22 The case law is clear. Companies are allowed to  
23 continue to be optimistic about their prospects. They do not  
24 need to disclose everything that happens. If every company  
25 had to disclose everything that could possibly put their

1 submission at risk, the companies would be making disclosures  
2 all the time that may actually impact their approvability of  
3 the submission by pointing it out.

4 But here the thing is, Your Honor, they all  
5 determined -- there was dialogue back and forth and they  
6 determined to submit. The truth is the reason I keep focusing  
7 on Martin's scienter and Smith's scienter is not because I'm  
8 trying to say that the highest levels of the organization  
9 should be allowed to put their head in the sand. I am saying  
10 I think we've gone far off track of who the speakers of the  
11 statements are and it is their scienter that matters and their  
12 scienter only under the case law.

13 Under the standards for securities fraud, there has to  
14 be scienter of the speaker. Martin didn't receive this  
15 e-mail, and it's not an issue for the jurors to decide whether  
16 he should have had scienter in the absence of seeing this  
17 e-mail because plaintiffs have to provide evidence to create  
18 an issue of material fact, and this is not evidence of  
19 Martin's scienter.

20 THE COURT: So you're saying there's no evidence that  
21 Lamb testified he shared his concerns with Martin?

22 MS. YADAVA: No, Your Honor.

23 THE COURT: None at all?

24 MS. YADAVA: Off the top of my head, I don't believe  
25 there is. But even if there was, Your Honor, let me just

1 reiterate my point from earlier. People can have differences  
2 of opinion and it does not make the speaker's mental state  
3 change.

4 THE COURT: March 15th, 2018, after the fact but it  
5 goes to what we knew beforehand.

6 Lamb: The FDA repeatedly stated what they expected.  
7 It was ignored and we got the RTF.

8 So it's after the fact but it's talking about what we  
9 knew beforehand. "We knew what the FDA wanted, we ignored it,  
10 we got the RTF." He doesn't say, "I ignored it." He says,  
11 "We ignored it. We got the RTF."

12 I know he's talking probably about Celgene in general,  
13 but obviously companies need people to work. So if I'm  
14 looking at an after-the-fact omission saying, "We ignored what  
15 the FDA wanted. We got it rejected," then you're going to say  
16 Lamb never shared that concern with Martin.

17 MS. YADAVA: Your Honor, these e-mails are all Monday  
18 morning quarter-backing. I think we can accept --

19 THE COURT: Monday morning quarter-backing is like --  
20 he's saying, "This is what we knew beforehand and we ignored  
21 it and we got an RTF." We can look at what somebody says  
22 about the past to determine what was their state of mind then.  
23 If they said, "I knew this was going to happen and we  
24 discussed this," that is not Monday morning quarter-backing.  
25 That's saying, "Hey, this was a risk we knew about, we ignored

1 it, and we got rejected."

2 MS. YADAVA: Your Honor, Lamb also signed off on the  
3 submission. This is what I can't -- there's a dichotomy  
4 between this that doesn't suggest --

5 THE COURT: Yeah, corporate pressure. I get it. I get  
6 corporate pressure. You've got to get it filed. "We have the  
7 FDA consultants, we think we'll get it through, all right,  
8 sign off on it."

9 I get it. I understand corporate dynamics and pressure  
10 to get things done. I got that. But when somebody is now  
11 saying after the fact, "We discussed this, we didn't do what  
12 the FDA wanted" and so forth, that's a genuine material issue  
13 of fact.

14 I'm not saying -- I don't know how it's going to come  
15 out. You can raise an argument and say Lamb signed off on it.  
16 That's an argument. They can say Lamb signed off on it but he  
17 knew that this was going to be a problem. That's an argument.

18 The jury may agree with you, they may agree with them.  
19 I don't know. I'm just looking if there's a genuine dispute  
20 of material facts.

21 You want me to start weighing in on these facts and  
22 ruling in your favor. I don't do that. You may wish -- I'm  
23 not saying you're going to lose. I'm just saying does this  
24 get past summary judgment.

25 MS. YADAVA: Your Honor, I think when you talk about

1 things like corporate pressure and all, I understand that  
2 there's a backdrop we can overlay, but there's no evidence in  
3 the record of any of that. There's no evidence --

4 THE COURT: Stop. Revlimid was running out. That was  
5 their whole theory. I always think of "The Devil Went Down to  
6 Georgia," right, because he was in a bind because he was way  
7 behind.

8 Revlimid is running out, you overpaid for three drugs  
9 and none of them worked out the way you thought. None of that  
10 is securities fraud. The question is, on two of them did they  
11 get to a point where you knew there was a problem and then you  
12 didn't fully disclose to the market.

13 Everybody knew Celgene had one big product, Revlimid,  
14 and the patent was running out. Look at your numbers for  
15 Revlimid compared to everything else. To say there wasn't  
16 corporate pressure just ignores the reality of what Celgene was  
17 facing as a company.

18 There was corporate pressure. There's not a doubt in  
19 my mind that there was corporate pressure. "We need to get  
20 new drugs in the pipeline to make up for the shortfall for  
21 Revlimid."

22 What else was Celgene going to do once Revlimid went  
23 off patent if they didn't have anything to supplement that  
24 amount of money?

25 MS. YADAVA: Your Honor, even taking that there was

1 corporate pressure for a second, filing a sloppy submission or  
2 a submission that people thought had a very high likelihood of  
3 rejection, which is what Your Honor had said before, doesn't  
4 help replace the revenue from Revlimid. But I hear you.  
5 Your Honor doesn't agree with my --

6 THE COURT: When you're under pressure, you do things  
7 you shouldn't do. Talk to your associates about their  
8 billable hours. People do things they shouldn't do when  
9 they're under incredible pressure.

10 We see that in the law. We talk about "Take care of  
11 yourselves." Right? "I billed 3,000 hours." It's like,  
12 okay, there's a pressure there that has nothing to do with  
13 what we learned in law school.

14 There are pressures, right, but the big pressure is,  
15 "Are we going to keep this organization going forward," and if  
16 so, "How are we going to do it?"

17 Unless I'm missing something, even on that when they  
18 changed the guidance, it was -- at that point in time Revlimid  
19 was 8 billion and the total revenue was 13 billion. It  
20 certainly seems as though they needed to come up with a way to  
21 make up that revenue.

22 MS. YADAVA: Your Honor, even if I accept that, which I  
23 will for Your Honor for the purposes of this argument --

24 THE COURT: You don't have to accept it, but that's a  
25 fact. I just read it to you. That's a fact. You don't have



1 to accept it. That's okay. You can tell me Revlimid wasn't  
2 that important to their portfolio. That's fine.

3 MS. YADAVA: I'm not saying that, Your Honor. All I'm  
4 saying is that the corporate pressure -- everyone who had to  
5 have signed off on the submission had to have believed that in  
6 the face of corporate pressure they were all going to buckle  
7 and all agree to the submission, but that doesn't even matter  
8 because the only speakers of the statements are Smith and  
9 Martin, unless we're going to apply corporate scienter, which  
10 should not be applied in this instance. There's no difference  
11 between the *Schwab* theory of corporate scienter and this one.

12 THE COURT: That's a fair enough point. Let me ask you  
13 on that point. I read the cases on corporate scienter. I  
14 realize it's a very difficult standard to reach.

15 Let me just ask you, though -- I know that plaintiffs  
16 also argued ultimate authority. Let me ask you, though, real  
17 quick what about -- I just focused on the statements based on  
18 your briefing.

19 What about plaintiffs' argument that the 10Q -- that's  
20 the July 27 10Q and that's a July 27 phone call. I went back  
21 to take a look at what plaintiffs pointed to in their  
22 complaint, but those seem to be July submissions.

23 Let me ask you generally, though, if they were going to  
24 point to an SEC filing, whether it be a Q, a K, or some other  
25 filing, what would be your view as to whether there was a

1 materially false statement or omission in the filing itself  
2 and who would be responsible for it.

3 MS. YADAVA: Your Honor, I don't think there are  
4 materially false statements in the filings, but in any  
5 event --

6 THE COURT: You might be right about that, but I'm just  
7 trying to figure out legally who could be responsible.

8 MS. YADAVA: Alison Kellogg signed the 10Qs and 10ks  
9 and you dismissed them as defendants in the first round of  
10 briefing.

11 THE COURT: Okay. All right, folks --

12 MS. YADAVA: Otezla?

13 THE COURT: We've got to talk about Otezla. Here is my  
14 issue with Otezla: Just to give you a smattering of  
15 examples -- and this is Exhibit 50.

16 Terri Curran writes: "Feedback, reference BOD deck.  
17 Don't like market share slide as it looks flat." Then she  
18 says, "Can we switch it to what we used historically?"

19 MS. YADAVA: Yes.

20 THE COURT: Then Exhibit 54, which is an EBR  
21 presentation in April of 2017, it says, "Q1 Otezla market  
22 shares relatively flat in both PsO and PsA." Those are the  
23 two different psoriasis that you've given me the abbreviations  
24 for.

25 I'm just trying to say that once she says, "We're

1 growing market share," just using that one as an example, but  
2 she's internally saying it looks like it's flat and there's  
3 another presentation saying they look relatively flat, using  
4 that as an example, why wouldn't that create a genuine dispute  
5 of material fact?

6 MS. YADAVA: Absolutely, Your Honor. I'm happy to  
7 address that.

8 Number one, if you look at that e-mail carefully that  
9 you just read to me, the first one about the feedback, she  
10 received feedback on a graphic that the slide -- the image in  
11 the slide looks flat. She's got her opinion. She's saying  
12 "feedback says." We don't refer to our own feedback in the  
13 third person.

14 It says she received feedback from someone else. This  
15 is a perfect example of plaintiffs pointing to e-mails and  
16 trying to ascribe them to Terri Curran's scienter when they're  
17 not indicative of her scienter at all. That's number one.

18 THE COURT: Wait a second. It's her e-mail and she's  
19 saying the feedback looks flat. So she disagreed with that  
20 statement? If she did, then why is she asking to change the  
21 slide deck?

22 MS. YADAVA: Your Honor, because the graphics --  
23 they're talking about the graphics for the slide  
24 presentations. You've seen probably the market share slide  
25 that was presented alongside her earnings call statement.

1           She's not happy -- someone, whoever is giving her the  
2 feedback, is not happy with how the graphic looks. It does  
3 not say anything about what she believes about market share.  
4 I will tell you the best thing --

5           THE COURT: Wait a second. It's her e-mail. She's  
6 conveying what people -- she doesn't say, "I disagree with it"  
7 or "Leave the slide as it is."

8           How can you say that doesn't say anything about what's  
9 in her state of mind?

10          MS. YADAVA: Because I don't think she's saying that  
11 she -- I don't think she's saying that the market share is  
12 flat or that anyone else is saying market share is flat. I  
13 think they're saying that the graphic -- the way that the  
14 graphic on the slide looks is showing market share is flat.  
15 They want to change the graphic because it's not looking good,  
16 but it's not looking good consistent with the data.

17          THE COURT: Because it's flat and they want to go back  
18 and use a historical analysis because it shows it's going up.  
19 The point is she says it continues to grow when internally  
20 she's been told it looks flat, and then they have a  
21 presentation that says it's relatively flat, but she says it  
22 continues to grow market share.

23          MS. YADAVA: Your Honor, three points in response.  
24 One, if you look at my reply declaration Exhibit 13, it is the  
25 contemporaneous e-mail that underlies her presentation from

1 that date. It's three days before.

2 It shows their numbers that they received at the time  
3 on market share and it shows that market share had gone up  
4 that quarter from 22.7 to 23.4 percent. That is an increase.

5 I will tell you, as we have said in our papers and as  
6 the only piece of evidence in the record shows, Terrie Curran  
7 was referring to market share in her statement over a  
8 two-year period.

9 THE COURT: No, no, no. That may be what the slide  
10 said, but she said, "It continues to grow." She's talking  
11 about the current time. She didn't say, "Historically we have  
12 grown since back in 2016." Her statement was that it  
13 continues. It's an ongoing basis.

14 MS. YADAVA: She testified she was meaning over time it  
15 continues to grow. But in any event, the data that underlies  
16 her slide, the data she received three days before says market  
17 share has gone from 22.7 to 23.4 percent, that is an increase.  
18 That is the only evidence of what market share was at that  
19 actual time.

20 THE COURT: No, it's not. She has a document saying  
21 it's flat. That's Exhibit 54, the EBR business summary.  
22 Quarter 1 Otezla market share is relatively flat in both PsO  
23 and PsA. She has other information, as well.

24 MS. YADAVA: Your Honor, the same slide that you're  
25 looking at, Plaintiffs' Exhibit 54 -- is that correct?

1 THE COURT: Yes.

2 MS. YADAVA: The same slide shows that it increased  
3 from April -- it says PsO market share increased from  
4 20.5 percent in April of 2016 to 23.4 percent as of  
5 March 31st, 2017. So even if we're talking about a shorter  
6 time period, this is why I'm saying a cherry-picked slide --  
7 I know Your Honor has said that we're doing the same thing but  
8 we are not.

9 THE COURT: It's not cherry-picking a slide. It's just  
10 that there's other evidence against what you're telling me.  
11 That's what I'm looking at. I'm like, you're saying this is  
12 what she was relying upon.

13 They're saying she had information saying it was flat,  
14 and now you want me to make the call. That's not what I do.  
15 You can argue and say, "Well, it actually did" -- whatever  
16 your arguments are, it was over a longer period of time,  
17 it was actually increasing here and so forth. And they can  
18 say, "Guess what, her information was it was flat. She said  
19 it continues to grow." That's a genuine dispute of material  
20 fact that the jury makes the call on.

21 MS. YADAVA: Your Honor, all I'm saying is saying that  
22 it's characterizing it as relatively flat but also have the  
23 underlying data in the presentation itself -- this is an  
24 opinion statement Your Honor has already held, so it has to be  
25 that she didn't honestly believe her statement or one of the

1 other *Omnicare* prongs.

2 Here there's data that she received three days before  
3 her presentation that shows market share increasing. If a  
4 reasonable investor had believed that she was referring to  
5 market share over a shorter time period or a bigger time  
6 period, it doesn't matter because that does not show that  
7 Curran had the intent to mislead the market or that she was  
8 grossly reckless in her statements.

9 THE COURT: So what changed from Quarter 1 to Quarter 2  
10 in her statements that caused you then in Quarter 3 to change  
11 your projections? It had to be -- I guess what you're saying  
12 is it had to be new information after Quarter 2 that they had  
13 in Quarter 3 to downgrade.

14 So what new information did they get after Quarter 2 to  
15 explain why they were changing their forecast?

16 MS. YADAVA: Of course, Your Honor. As Celgene  
17 explained to the market, the market didn't grow as much as  
18 Celgene had expected it to. It has nothing to do with market  
19 share.

20 Plaintiffs focus a lot in loss causation about market  
21 share and market growth somehow being intertwined. Those are  
22 distinctive metrics. One can rise without the other; one  
23 could fall without the other as well.

24 Loss causation means you have to reveal the falsity of  
25 something that was said. There's nothing in the record that

1 shows that those are the same metrics.

2 THE COURT: Okay. Exhibit 36, 3/24/2017 e-mail  
3 explaining why you didn't hit your Quarter 1. Demand. Market  
4 growth has slowed down.

5 It certainly seems as though she knew that the market  
6 growth slowing down wasn't new information because she had it  
7 back at that time.

8 MS. YADAVA: That was market growth in Q1. They were  
9 predicting market growth in Q3 to grow that it didn't. Q1 we  
10 know was a bad quarter. Everyone admits it. Celgene  
11 publically explained --

12 THE COURT: No, no, no. You're saying what changed  
13 was -- you've been arguing there's a difference between market  
14 growth and market share. I understand the difference in  
15 market growth and market share.

16 You're saying she only talked about market share even  
17 if market growth was declining. You said now in Q3 we have  
18 market growth declining. She knew in Q1 market growth was  
19 declining and that's the key point.

20 You said there's no evidence that they knew of that.  
21 She knew it.

22 MS. YADAVA: Your Honor, that's not what I intended.  
23 What I'm trying to explain is that in Q2 the market did grow.  
24 When she made her statement, there was market growth. In Q3  
25 the market did not grow. That's the information that changes



1 between Q2 and 3. The market did not grow as much as what was  
2 predicted.

3 So the issue here is that -- this is why -- you know,  
4 Mr. Kravetz said it keeps going back to loss causation. She's  
5 opining in Q2 about why she believes net sales will rebound.  
6 She says, "Based on the run rate from Q1 to Q2, here is why I  
7 think net sales will rebound," and she points to all of the  
8 factors.

9 What happened in Q2 and what she believes is going to  
10 happen in Q2 is not directly related to what happens in the  
11 corrective disclosure in October in Q3. One is not revealing  
12 the falsity of the other.

13 They could still have been on track in April, based on  
14 the metrics and the guidance she got from others at the  
15 company, but they were on track to hit their guidance at that  
16 time but circumstances can change, which is exactly what  
17 Celgene explained to the market in October.

18 "Circumstances changed. The market did not grow as  
19 much as we thought and the discounts tied to managed-care  
20 strategy affected our overall numbers more than we expected."

21 THE COURT: I need to rule on this motion, but let me  
22 just give both sides an opportunity to give me their closing  
23 arguments. I'm going to take a 10-minute break and I'll come  
24 back and rule.

25 (Recess taken.)

1 (All parties present.)

2 THE COURT: Okay, counsel, let me hear -- I'll give  
3 everybody -- I'll give defendant -- I'll give both sides  
4 five minutes to give me their closing. I'll let plaintiffs  
5 decide how they want to split among counsel, and then I do  
6 have to get the ruling going.

7 Let me hear first -- let me go right in order.  
8 Ms. Yadava first, Mr. Zivitz, and then Mr. Kravetz. Before I  
9 go any further, I want to thank everybody. I know we have to  
10 ask the pointed questions, but I greatly appreciate the  
11 preparation of all counsel and the submissions. It was a very  
12 big record, but stepping back from my role of deciding this  
13 motion, I want to thank counsel for the excellent work in this  
14 case.

15 I'll let Ms. Yadava go first.

16 MS. YADAVA: Thank you, Your Honor. I think I'll be  
17 less than five minutes.

18 THE COURT: Okay.

19 MS. YADAVA: I'm just going to emphasize a few points,  
20 beginning with ozanimod.

21 Your Honor, corporate scienter is not available in  
22 these circumstances. Plaintiffs continue to point to cases  
23 like *Cognizant* where the facts and allegations were entirely  
24 different.

25 There was alleged a criminal bribery scheme, there were

1 indictments and the like. Nothing of that sort is alleged  
2 here. In fact, there weren't even blatantly false statements.  
3 Even if the corporate scienter doctrine were to apply, it  
4 requires a culpable act by someone with scienter. We don't  
5 have that in this situation.

6 Similarly, Your Honor, we talked about scienter and  
7 differences of opinion within the company, but the truth is  
8 all that this was and the record evidence shows were  
9 differences of opinion within the organization. The case law  
10 is clear that differences of opinion do not establish  
11 scienter.

12 Your Honor, you mentioned earlier a hypothetical about  
13 your law chambers, and I was thinking about there are law  
14 clerks who are working with you on an opinion and they exhibit  
15 dissenting views. It doesn't necessarily change your mind  
16 state. It doesn't make you think something differently than  
17 you thought initially.

18 So here, Your Honor, there's nothing other than  
19 dissenting views that do not reflect on any of the individual  
20 speakers' actual mental state.

21 On Otezla, I'll make two final points, beginning with  
22 loss causation. There is a clear disconnect between the  
23 contents of the statements in April, the contents of the  
24 statements in July, and the alleged corrective disclosure.

25 The alleged corrective disclosure addressed what

1 happened in Q3, what happened such that Celgene was no longer  
2 able to meet its guidance. It does not address what was  
3 happening in terms of run rates between Q1 and Q2 and it did  
4 not address market share and prescriber adoption in Q3. There  
5 is an entire disconnect between those two.

6 Your Honor has said himself in the *Aurora Cannabis*  
7 case, contrary to what plaintiffs keep saying today, that this  
8 is an issue for the jury. There are circumstances when it is  
9 not. There are circumstances in which the analysis is clear  
10 that loss causation does not apply and that is one of these  
11 instances.

12 THE COURT: Let me just ask you on that issue, though,  
13 whenever a company misses earning statements, unless there's  
14 something criminal that occurred, as you pointed out -- I'm  
15 not saying this is criminal. This is a civil case.

16 But do companies when they miss earnings statements  
17 ever say, "Hey, by the way, what we told you in our other  
18 two quarters, you know, that wasn't right"? It's one of those  
19 things it seems to me you would never have loss causation  
20 under your theory because the company is going to say, "We  
21 missed our earnings statements, we're going to have to  
22 downgrade, but it's for new reasons."

23 It seems to me you're saying almost as a matter of law  
24 there can't be loss causation in this case.

25 MS. YADAVA: I'm not saying that, Your Honor. I'm

1 saying that the reasons that Curran articulated in Q2 for a  
2 rebound in sales between Q1 and Q2 that showed net sales on  
3 track to meet the guidance are different than what happened  
4 in Q3.

5           There's a lot of case law out there that explains that  
6 just because a company does not hit its guidance does not make  
7 all statements about that guidance or about those sales  
8 fraudulent, and this is exactly one of those instances.

9           THE COURT: I don't disagree with that as a proposition  
10 of law. I'm just saying that plaintiffs' view is -- in their  
11 view, the material misstatements or omissions earlier, if she  
12 had told accurate, those also contributed -- let's say just  
13 contributed. I don't want to say necessarily a sole cause but  
14 contributed to why they had to change their guidance. The  
15 reason I point that out is it seems like that's a question of  
16 fact for the jury to decide as opposed to as a matter of law.

17           MS. YADAVA: I don't think so, Your Honor. I think in  
18 October the corrective disclosure has to reveal some falsity  
19 of those alleged misstatements, and when they are apples and  
20 oranges comparisons that do not line up -- *Goldman Sachs*, the  
21 new Supreme Court case, talks about a mismatch between the  
22 alleged misstatements and the corrective disclosures.

23           This is similar here. They might both be about sales  
24 but there is a mismatch between what they are talking about in  
25 terms of sales and the underlying metrics.

1 THE COURT: Okay. Thank you.

2 MS. YADAVA: Of course. My final point will be on  
3 scienter for Otezla.

4 I know Your Honor thinks there's a lot of evidence in  
5 the record that may show a question of fact about falsity, but  
6 even if reasonable investors took Curran to be meaning  
7 something else than what she said she was intending to say,  
8 plaintiffs have to show that it is an extreme departure from  
9 the standards of ordinary care.

10 In the Third Circuit, this is an extremely high bar.  
11 They have to show not just that she disregarded other people's  
12 opinions but that it was entirely reckless to go forth making  
13 a statement to the market about run rates out of Q1 into Q2  
14 and to make a statement about what market share and prescriber  
15 adoption are doing in the face of the charts that were also  
16 presented at the very same time, which I think negates the  
17 inference of scienter as well.

18 For all those reasons, we believe that defendants  
19 should be granted summary judgment in its entirety.

20 THE COURT: Thank you, Ms. Yadava. Very good job  
21 arguing. Thank you.

22 MS. YADAVA: Thank you.

23 THE COURT: Mr. Zivitz.

24 MR. ZIVITZ: Thank you, Your Honor. Thank you and your  
25 team for all of the time you guys have spent on this. We

1 recognize it is in fact a massive record and obviously a lot  
2 of time.

3 THE COURT: I wouldn't mind. My hourly rate is just  
4 a lot lower than yours. That's what it is. Go ahead.

5 MR. ZIVITZ: Your Honor, we have covered a lot today.  
6 I will be brief. The very fact that we have been going for  
7 two hours, the amount of paper that is before Your Honor, you  
8 can tell that -- at least our view, Your Honor, respectfully  
9 is that issues of fact abound here with respect to ozanimod.

10 I just want to read something that Your Honor held at  
11 the motion to dismiss stage, just to launch into my last  
12 point, which is you held at the motion to dismiss:

13 (Reading.)

14 To make the public disclosures concerning the  
15 NDA legally accurate, Celgene -- Celgene was  
16 required to also disclose meaningful information  
17 as to the metabolite vis-à-vis the NDA.

18 Our position, Your Honor, is that Celgene is its  
19 people. Right? I listed them earlier. I think it's worth  
20 listing them again.

21 At various points in time throughout the class period  
22 and certainly by July, you have evidence showing that Smith,  
23 Terry Curran, the head of I&I; Martin, Saillot, Jay Backstrom,  
24 the chief medical officer; Matthew Lamb, the global head of  
25 regulatory affairs; Maria Palmisano, corporate vice president,

1 clinical pharmacology; Gondi Kumar, vice president  
2 non-clinical development, and other high-ranking officials  
3 knew in the company about the metabolite and they knew of the  
4 risk that arose from the metabolite.

5 As that July 26 and 27th e-mail recognized, this has  
6 potential for major implications for the submissions. This  
7 was a material omission that the jury should be able to  
8 determine whether the company had a duty to disclose.

9 Your Honor, just getting back to the Celgene point -- I  
10 want to be precise on this. There are SEC filings throughout  
11 the class period. Starting in July there's a 10K, there are  
12 multiple 10Qs, there are 8Ks containing press releases, there  
13 are corporate slides published on the company's website. They  
14 are all corporate statements.

15 As I mentioned, a corporation operates by its people.  
16 Martin and the list of folks I ran through, their scienter is  
17 imputed to the company for purposes of those statements.

18 I know Ms. Yadava focused on the *Cognizant* and  
19 *Roseville* cases. First of all, again, those are pleading  
20 cases.

21 Here we have hard evidence of actual knowledge by  
22 upper-level management. And even under the *Cognizant* test,  
23 Your Honor, all of those individuals furnished misinformation  
24 to management and they tolerated the misstatements after they  
25 were issued.



1           That is the test under all three tests that *Cognizant*  
2       lays out for purposes of imputing scienter to the company for  
3       all of the statements.

4           So, Your Honor, I know we talked about April. Again,  
5       I'll concede that April is the weakest of our grouping of  
6       statements, but certainly by July you have a host of  
7       high-level management that knew about the metabolite, knew  
8       about the risk.

9           Their scienter is imputed to Celgene for purposes of  
10      holding those statements in. And those statements, frankly --  
11      you know, based on, as Your Honor noted the standard, there  
12      are genuine issues of fact here. So we respectfully submit  
13      that those statements certainly should go to the jury.

14           Your Honor, again, thank you your time. Unless the  
15      Court has any questions, I'm done.

16           THE COURT: No. I'm good. Thank you.

17           MR. KRAVETZ: Your Honor, Robert Kravetz on behalf of  
18      plaintiffs. I have nothing further on behalf of Otezla. I  
19      appreciate having the opportunity to appear in front of  
20      Your Honor. Thank you.

21           THE COURT: Thank you.

22           For both counsel, too, Mr. Kravetz and Mr. Zivitz,  
23      thank you for doing a very good job.

24           MR. KRAVETZ: Thank you, Your Honor.

25           THE COURT: Before I get to Otezla, I just want to

1 acknowledge some of the standards that counsel have been  
2 referencing but that I'm using to review the current matter.

3       There was a dispute in the papers as to the standard I  
4 should apply as to opinion and whether the *Omnicare* standard  
5 applied. Just by way of background, the standard before  
6 *Omnicare* was an opinion was not actionable unless it was not  
7 honestly believed and also lacked a reasonable basis.

8       *Omnicare* changed. It did so in the Securities Act,  
9 section 11 of the Securities Act. The defendants are correct  
10 that the Third Circuit has not formally adopted the *Omnicare*  
11 standard to the Exchange Act. They reserved on it.

12       The case that most people cited to -- and I'm going to  
13 spell it because I have difficulty pronouncing it -- is  
14 J-A-R-O-S-L-A-W-I-C-Z, 912 F.3d 96, Third Circuit, 2018.

15       The reason the circuit did not decide whether the  
16 *Omnicare* standard applied was because they said, "Even if we  
17 did apply the *Omnicare* standard, plaintiffs still fell short,"  
18 or at least that portion of the opinion, because it went up on  
19 appeal again. That's at 962 F.3d 2020.

20       Now, in that case, the circuit just said -- without  
21 saying it was deciding, it said that *Omnicare* provided the  
22 relevant framework as to evaluating opinions.

23       So under the *Omnicare* standard, opinions are actionable  
24 if the statement falsely describes speaker's own state of  
25 mind, the opinion includes untrue embedded statement of fact,

1 or the speaker admits material facts about her inquiry into or  
2 knowledge concerning a statement of opinion and such facts  
3 conflict with what a reasonable investor would take from the  
4 statement.

5 As to scienter -- I know that Ms. Yadava mentioned the  
6 standard, but let me just make clear it's a knowing or  
7 reckless standard. Knowing is that you knew what you were  
8 saying was false or misleading. Recklessness has to be more  
9 than simple or inexcusable negligence. It has to be extreme  
10 departure from the standards of care which presents a danger  
11 of misleading buyers or sellers that is either known to the  
12 speaker or so obvious that the actor must have been aware of  
13 it and it does approach conscious deception.

14 Now, turning to Otezla briefly, because the parties are  
15 well aware of the facts. But at the relevant time Ms. Curran  
16 was the president of worldwide markets I&I for inflammation  
17 and immunology until April 1st of 2017. She then became the  
18 president of Celgene I&I and the chairwoman of the IIEC, the  
19 Inflammation and Immunology Executive Committee.

20 I've used a couple of definitions that I would like to  
21 make clear on the record. PsA, which is psoriatic arthritis,  
22 and then also PsO, which is plaque psoriasis.

23 The two statements that are at issue, the first  
24 concerns April 27th of 2017. Ms. Curran was on a first  
25 quarter 2017 earnings call and there was also a press release.

1 I believe at that time the sales -- the sales were obviously  
2 down. That was the reason there were questions asked. I  
3 believe it was 21 percent less than Otezla net sales for the  
4 previous quarters which would have been the fourth quarter of  
5 2016.

6 The statement at issue came up because a UBS analyst  
7 asked about whether sales would bounce back or whether they  
8 would see continued pressure in the near term. The parties  
9 have the statement.

10 Some of the key points of the statement by Ms. Curran  
11 was that she found that there were really three key drivers to  
12 the performance in the first quarter. First: "Contraction in  
13 the market as we saw increased GTN, gross-to-net ratio, as a  
14 result of contracting, but importantly that really gives us  
15 access to double the number of insured lives going forward."

16 And she also said, "We saw minimal drawdown of  
17 inventory."

18 She said, "If we look at the underlying dynamics of the  
19 business, they are exceptionally strong. If you look at the  
20 market share, Otezla continues to grow market share."

21 I want to make clear that when I'm looking at this  
22 evidence I'm just trying to determine whether there is a  
23 genuine dispute of material fact. I am not weighing the  
24 evidence, I'm not making credibility calls, but I'm trying to  
25 determine whether this should get to a jury. I don't know

1 what the jury is going to do.

2 We talked about -- I have the deck here, which  
3 Ms. Yadava said is Plaintiffs' Exhibit 50. On April 14th,  
4 2017, Ms. Curran writes an e-mail in which she writes:  
5 "Feedback, reference BOD deck. Don't like market share slide  
6 as it looks flat. Can we switch it to what we used  
7 historically?" which is ultimately what did happen.

8 Defendants are free to argue, "Well, that wasn't really  
9 her view. She was just a conduit of information," but at the  
10 same time plaintiffs are free to argue that she put it in an  
11 e-mail, she thought it was important, she was the one giving  
12 the presentation, and she didn't say she disagreed with that  
13 statement.

14 The point is is that it does look flat. And then  
15 Exhibit 54, right, so you have the April 2017 -- you have an  
16 internal statement that Q1 Otezla market share is relatively  
17 flat in both PsO and PsA.

18 Again, defendants are free to argue, "Yeah, but it was  
19 technically true. They said 'flat,' didn't really mean  
20 'flat,'" but to me that's a traditional dispute that goes to  
21 the jury as to "When you said 'flat,' did you mean flat or not  
22 really flat?"

23 I'm not being facetious here. Sometimes people use  
24 terms and they say, "Well, I didn't really mean we didn't  
25 grow. We did grow a little bit, but it wasn't what we were

1 expecting."

2 I'm not at all being dismissive of defendants'  
3 arguments. They may prevail on that point. Plaintiffs may  
4 prevail on that point, but the point is there's an issue there  
5 that I think would be appropriate for the jury to determine as  
6 opposed to trying to do it on summary judgment.

7 That's what I did when I went through this file. When  
8 she said she saw a minimal drawdown in inventory, plaintiff  
9 has an explanation, that Ms. Curran was talking about the  
10 total of inventory drawdown and so forth, as to what she  
11 meant. I'm sorry, defendant set up an explanation there.

12 Plaintiffs have a different view. They point to  
13 evidence that actually that wasn't accurate. The first  
14 six weeks of the year inventory drawdown to mid-single digits,  
15 days on hand, again saying that's within the realm of normal.  
16 I believe that was Exhibit 67.

17 But the point being is that there is contrary evidence  
18 to what Ms. Curran said at that time and those are generally  
19 contemporaneous documents that were not only available to  
20 Ms. Curran but Celgene at the time.

21 The underlying dynamics are exceptionally strong.  
22 Exceptionally strong, I do agree, is a puffery term, but the  
23 underlying dynamics is not, in my view. Now, of course, you  
24 know, that is open to interpretation where defendants can say,  
25 "This is what we meant by underlying dynamics." And

1 plaintiffs can say, "This is what the underlying dynamics  
2 are."

3 But, again, looking at I believe Plaintiffs'  
4 Exhibit 67, 54, 64, there is a genuine issue of material fact  
5 as to whether or not the underlying dynamics -- I don't know  
6 if you could say exceptionally strong, strong, but were they  
7 somewhere in that realm of what she was describing at that  
8 point.

9 She also said, "Seeing net sales rebounding and on  
10 track with 2017 guidance." There was evidence Q2 was better,  
11 that net sales were better, but what plaintiffs point to are  
12 exhibits and internal documents where they were saying, "We  
13 are bouncing back, but we are still not increasing to the  
14 level to make up the first quarter shortfall."

15 Then there's that question as to were you actually  
16 going to be able to make up the shortfall. I don't think  
17 anybody disputes that net sales were better in the second  
18 quarter. The question is were they good enough to hit the  
19 forecasting budget. That would be a genuine dispute of  
20 material fact.

21 Ultimately, once I find that there are genuine disputes  
22 of material fact, it's very hard for me as a judge to start  
23 ruling on scienter as a matter of law because now I have to  
24 determine what was going through her mind when she said that.

25 Plaintiffs may be right -- defendants may be right. At

1 most it was simple negligence, which in case they're not  
2 actionable. But defendants [sic] may be right, this was  
3 reckless disregard of the information.

4           Ultimately, the jury is going to be given that  
5 instruction, and that's what the plaintiffs are going to have  
6 to prove if they want to succeed. But to do it as a matter of  
7 law -- you know, I just say this as an aside and I only say it  
8 because I know Mr. Cecchi and Mr. Lustberg and I know their  
9 practices, but I read the argument where, you know, "Well,  
10 Ms. Curran testified that it was an honestly held belief and  
11 so that's all there is to it."

12           I just thought of Mr. Lustberg in my prior life that if  
13 it were only that easy in securities fraud criminal cases to  
14 say, "We didn't have the intent to defraud and Rule 29, Judge,  
15 in our favor," but it's very difficult on the record to try to  
16 determine what was going through her mind at that time.

17           I do agree that the Third Circuit said this is  
18 generally going to be an issue of fact for the jury. That  
19 just comes from a different world because it would make  
20 defending fraud cases a lot easier if your client could just  
21 say, "I didn't intend to defraud anybody," and you're like,  
22 "Okay, let's get out of here."

23           Unfortunately, we know that's not the way it works for  
24 criminal defense counsel. This is not a criminal case. I  
25 want to make that clear. I don't see any evidence of



1 criminality here. I'm not trying to suggest it. That was  
2 just by way of analogy.

3 Similarly as to loss causation, I believe it's an issue  
4 of fact for the jury to decide. I know that the defendants --  
5 "These are the reasons why we had to change our guidance."

6 Plaintiffs have given evidence saying, "No, there were  
7 other reasons that you knew about when you made the first  
8 statement at first quarter and the second statement in the  
9 second quarter, and those were contributing factors if not the  
10 factors" -- I could see how they argue it to a jury -- "as to  
11 why you had to change your guidance."

12 Ultimately, if defendants are right that nothing that  
13 Ms. Curran said, even if it was incorrect, impacted why they  
14 had to change their guidance, the defendants prevail because  
15 plaintiffs did not prove loss causation.

16 But if plaintiffs are correct that these were  
17 contributing factors or the factors or whatever it may be,  
18 then they prevail. But that's their burden and that's what  
19 they're going to have to show at trial. But to say as a  
20 matter of law that the defendants' stated reasons were the  
21 only reasons, I just can't do it on this record.

22 Similarly, with the July 27th, 2017, opinion, that was  
23 not in response to a question. That was her remarks. But,  
24 again, the parties have it, briefly: "Q2 was an outstanding  
25 quarter for Celgene I&I highlighted by significant sequential

1 growth for Otezla. Key Otezla performance indicators continue  
2 to strengthen and market share and prescriber adoption  
3 increase significantly in both the U.S. and internationally."

4 Again, talking about gains and treatment adoption: "We  
5 have advanced multiple future growth drivers for Otezla" and  
6 so forth.

7 Now, again, the question for me is a genuine dispute of  
8 material fact. We know that that turned out not to be an  
9 accurate statement based on what happened afterwards, but the  
10 question is what was going through Ms. Curran's mind at the  
11 time, and that's because they had to revise their guidance in  
12 the third quarter.

13 Again, there have been -- for example, PX-60 there's  
14 indication that the underlying data shows that there was a  
15 decrease in market share. We've talked about the difference  
16 between market growth and market share. They are very  
17 different. You can increase your market share in a  
18 contracting market, you can decrease your market share in a  
19 growth market.

20 I know that those are two different things.  
21 Ultimately, the overall market growth was one of the stated  
22 reasons for having to change the guidance from 1.5 to --  
23 approximately 1.8 billion down to 1.25. But I understand the  
24 difference between the two.

25 The key performance indicators, again, that's the

1 statement she used. Defendants can argue to the jury this is  
2 what she meant by key performance indicators.

3 Plaintiffs can argue this is what key performance  
4 indicators are in the industry, but they have presented  
5 evidence that based on what at least appears to be sound  
6 reasoning that a reasonable investor would consider to be  
7 performance indicators that there was information to the  
8 contrary, that they were not supporting that statement.

9 So for that reason I find there's genuine disputes of  
10 material facts as to her two statements. Again, scienter and  
11 loss causation as to both.

12 I do not find it appropriate for summary judgment. I'm  
13 going to deny the motion for summary judgment as to  
14 Ms. Curran.

15 By the way, before I forget, I did not prepare today  
16 because I didn't see it in the briefing as to these arguments  
17 as to the SEC filings, 8Q, 10K, 10Qs. That's not the way I  
18 read the defendants' motion. I didn't see opposition.

19 So when I issue this order, I'm going to issue an order  
20 based on the motion for summary judgment that the genuine  
21 disputes of material fact preclude summary judgment. I'm  
22 going to say there's not genuine disputes of material fact  
23 that don't preclude summary judgment as to these statements.

24 If plaintiffs believe they're still part of their case  
25 that's alive based on these other filings, I will note that my

1 summary judgment motion is limited to those. It seems to me  
2 that the defense' position is those are not issues.  
3 Plaintiffs believe they are issues.

4 I'd have to go back through the pleadings and see how  
5 the case was litigated to make that determination, but it's  
6 not the issue that was before me in deciding this.

7 Turning to ozanimod, ozanimod was developed by  
8 Receptos, Inc. In August of 2015 Celgene acquired Receptos.  
9 Martin was the managing director of Celgene Receptos from 2016  
10 to March 2018. Until April 2016 he reported directly to  
11 Smith.

12 Smith was the president of Celgene I&I and the chairman  
13 of IIEC from 2010 to April of 2017. He then in April of 2017  
14 became the president and COO of Celgene and was no longer a  
15 member of the IIEC.

16 Turning first to the April 27th, 2017, Q1 earnings  
17 call, I agree with the defense that there's no genuine dispute  
18 of material fact that at that time -- and I wanted to pull up  
19 a specific exhibit because it was referenced a lot in the  
20 papers -- it was not argued here today -- that Celgene had  
21 even confirmed the existence of the metabolite to be sure.

22 They realized on the testing that there could be a  
23 metabolite and they were organizing as to "What do we do if  
24 there is a metabolite?" but there was no definitive  
25 determination that there was in fact a metabolite.

1 I just haven't seen any cases that when you have a  
2 concern that something may come to fruition but you haven't  
3 verified it that that is now material non-public information.  
4 That I agree with Ms. Yadava.

5 If you had to go out and say, "We identified something,  
6 we don't know what it is but it could be bad," it would make  
7 the disclosure obligations extremely difficult and it would  
8 send the company's stock potentially into a tailspin over an  
9 issue that really doesn't exist if it turns out it's not, in  
10 this case, a metabolite.

11 Let me just get the exhibit that was given to me.

12 (Brief pause.)

13 THE COURT: One of the arguments that was made  
14 extensively in the briefing by plaintiffs that when I went  
15 back and looked at the actually document -- let me just give  
16 you an example.

17 Plaintiffs' Exhibit 108, that's March 30th of 2017.  
18 It's a long e-mail to a number of members. It talks about,  
19 "Sorry for the delay, but attached you will find the NDA  
20 submission tracking dashboard."

21 Even there, as of March 27th, all internally it  
22 indicates is there's a potential to identify a new metabolite.  
23 Even at that point internally they're acknowledging there may  
24 be a new metabolite but they have to identify it, and it says  
25 why. "The preliminary data from plasma samples in the 1909

1 study is expected by the end of this week to possibly provide  
2 a clue about any potentially new metabolite for RPC1063.  
3 Actual data will be available in early May."

4 At that point they were still trying to determine  
5 exactly what they had. They knew it was a potential, and  
6 that's the same on Plaintiffs' Exhibit 111. It's an e-mail  
7 April 24th of 2017, where the status update says, "It appears  
8 that this new peak is real." That's what gave them concern  
9 they may have a metabolite. "It's unclear whether it is a  
10 single peak, but we are assuming that it is a single peak."

11 Then it talks about what happens if the metabolite is  
12 present, if it's not present. So they're still making plans  
13 at this point that if it is a metabolite and it is present,  
14 this is how they plan on addressing it. But there still was  
15 no confirmation that it was in fact a metabolite.

16 For that reason, I don't find there's a genuine dispute  
17 of material fact as to Smith's statements in April of 2017  
18 because it wasn't even clear internally to Celgene Receptos  
19 that they did in fact have a metabolite.

20 The next statement in July that Smith made -- by the  
21 way, Smith just tended to say -- he liked the word "very."  
22 "Very, very, very, good. On track for filing" and so forth.  
23 He did not give a lot of specifics and he used a lot of  
24 "verys."

25 But what I will note is that the only evidence I have

1 is that e-mail from Martin to Smith right before he gave the  
2 statement. It's Plaintiffs' Exhibit 122. I heard the  
3 plaintiffs' argument that this could be interpreted  
4 differently. It's July 25th of 2017.

5 Certainly what's disclosed to Smith is that there is a  
6 metabolite. It has been confirmed. However, there's no  
7 indication to Smith that it's going to affect the NDA process  
8 adversely or that it could impact the NDA process adversely.  
9 It follows up with -- after that it says, "Preliminary data  
10 indicates that our story remains intact and that approvability  
11 is not impacted by this new finding. All the activities that  
12 could be done to qualify have been conducted or are ongoing  
13 and recent feedback from FDA reviewers" -- that's the FDA  
14 consultants -- "indicates that our plan data should be  
15 acceptable to the agency and allow us to keep the submission  
16 on schedule."

17 That's what Smith had. I know that there's the e-mail  
18 about the material information, I know there's a reference  
19 that somebody thought Smith had known about it, but I don't  
20 have any definitive evidence that Smith in fact knew about  
21 this internal concern.

22 That's what I need to do first before I start  
23 interpreting what that e-mail could mean, if I'm looking at it  
24 in the light most favorable to the plaintiffs, which I have to  
25 do in this case.

1 I know that defendants have a different interpretation  
2 of the e-mail, but it certainly gives a basis to ask the  
3 writer as to "Why did you think Smith knew about it?" And  
4 then depending upon what that person said, it might be enough  
5 to be considered at this stage, at the summary judgment stage.

6 But I don't have any information that he was in fact  
7 informed. Somebody thought he was informed, but there's no  
8 information that he was in fact informed.

9 So for that reason I'm going to grant summary judgment  
10 as no genuine dispute of material facts exist as to Smith's  
11 July 27th statement.

12 That leaves us to the October statement. I view that  
13 differently. I do want to say that I -- I actually disagree  
14 with the law here, but I'm going to follow the law. I  
15 have to.

16 I agree that this is not a case of the corporate  
17 scienter doctrine, if the Third Circuit were going to adopt  
18 it, that it would even apply in this case. It's not criminal  
19 activity.

20 It's not as though: "We're going to put this drug on  
21 the market and it's going to kill a lot of our patients." We  
22 don't have potential criminal activity. This is: Will the  
23 NDA be accepted by the FDA?

24 It may be civil liability, but as far as any type of  
25 far-ranging criminal activity, it just doesn't exist. My



1 disagreement with the law is, I think when the head of the  
2 company speaks, as Smith did here, what I think the law should  
3 be is he has a reasonable duty to do due diligence before he  
4 speaks. I don't think there should be this roadblock "If we  
5 don't tell Smith, he can't be liable for it."

6 I strongly disagree with that, but that is essentially  
7 the way the law stands. I have to show that the information  
8 was in Smith's head when he made the statement.

9 I don't like -- it personally bothers me that the heads  
10 of companies can insulate themselves from getting potentially  
11 bad information and then say, "Well, I'm not liable for what I  
12 said."

13 So in my view, the securities law should say if you are  
14 going to speak on behalf of the company, then you have a duty  
15 of reasonable diligence and inquiry so that then those other  
16 statements could be attributed to him because he didn't do his  
17 reasonable diligence and inquiry. I would do it under a  
18 reckless prong, obviously not knowing because he didn't know  
19 about it.

20 That's not what the law is at this time, but it really  
21 bothers me that -- I see these cases over and over again that  
22 the primary spokesperson, leader of the company, didn't know  
23 or at least I don't have information showing that he knew  
24 about these potential problems with the NDA submission.

25 That being said, I agree with Ms. Yadava that I don't

1 have anything in the record that Smith was aware of these  
2 internal concerns with the NDA submission. I want to put it  
3 in that term. I don't view this as every little problem has  
4 to be disclosed.

5 I agree with that as a proposition, but this wasn't a  
6 little problem. This was a product that they made public  
7 statements about when the NDA was submitted. It was clear it  
8 was going to be year-end of 2017. It was very important to  
9 Celgene because they were touting it.

10 So I don't view that as a little problem, but what I  
11 do agree with the defendants on is that this is more just  
12 disagreement. Disagreement could be, you know, do you put  
13 your client on the stand or not? Right? You have a  
14 disagreement about that.

15 This was there were internal voices directly involved  
16 with the product saying that this may not go through. It was  
17 a real risk that was understood by those working on the  
18 project within the company, and not a metaphysical risk, not a  
19 philosophical risk, but a real risk.

20 Ultimately, we know that the risk turned out that they  
21 got the RTF. Right? So that's what occurred here.

22 But I do agree with the plaintiffs that, given Martin's  
23 role in the company and his involvement with the project and  
24 the people all working around him, that it is a reasonable  
25 inference that Martin knew that this submission was at risk.

1           As plaintiffs correctly point out -- let me get the  
2 timeline correct.

3           (Brief pause.)

4           THE COURT: The day after the first statement in  
5 October when they did the briefing book, Exhibit 149, to the  
6 FDA, Celgene was basically asking the FDA to let them submit  
7 this information later concerning the metabolite. So not only  
8 was it an internal discussion and they knew that the FDA in  
9 general required the long-term studies -- I'm just going to  
10 use that term, "LTS," because that's what people use. I've  
11 seen other terms as well. I'll just use "long-term studies"  
12 on the metabolite, generally what they require in an NDA.  
13 They knew that they were asking for something different than  
14 that from the FDA.

15           It's in the briefing book. It's explicitly indicated  
16 to the FDA: "We're going to be asking" -- in my words -- "an  
17 exception to your general rule."

18           At a minimum, then, once Martin speaks and he talks  
19 about the positive top-line data, I do believe the material  
20 omission at that point was to say, "By the way, you know,  
21 however" -- it had to be couched in legal terms, I  
22 understand -- "we are going to ask the FDA to do something  
23 that they generally don't -- that their policy -- it would  
24 have to be an exception to the general policy. If the FDA  
25 doesn't accept our request, there's a risk that the NDA will

1 be rejected."

2 I think that's what had to be disclosed to the market,  
3 that this was, in my words, an at-risk NDA submission. I know  
4 that you can say philosophically every NDA is at risk because  
5 you don't know what the FDA is going to do, but there's a  
6 difference between knowing going into it that there's a  
7 potential problem and then getting feedback from the FDA that  
8 you didn't see coming and you have to go back through other  
9 steps as well.

10 So I will permit the Martin statement to go forward.  
11 Much to my chagrin, because I don't think the president and  
12 COO should be able to get a pass on these types of statements  
13 but I don't have evidence that I can point to to say Smith had  
14 this information when he made these statements -- should he  
15 have had that information? In my view, absolutely, but that's  
16 not the standard that I'm applying at this time.

17 So I'm going to grant the summary judgment motion as to  
18 Smith's three statements. I'm going to deny it as to Martin's  
19 statements.

20 Then, similarly, as to scienter, for the reasons I  
21 stated earlier, it's an issue of fact. Again, defendants may  
22 be correct, maybe this is not something that Martin thought  
23 it was that important; plaintiffs may be correct, he had to  
24 know this was important based on the discussions and should  
25 have been disclosed, that will go to his scienter.

1           And then similarly there is loss causation. I have  
2 addressed those filings earlier. It's an issue of fact, in  
3 my view. I can't say as a matter of law that I have to cut  
4 the loss causation out earlier.

5           Plaintiffs have given me enough that they can go to the  
6 jury with those other disclosures and argue that these were  
7 the corrective disclosures. I'm not saying a jury will accept  
8 those, but I think they have given me enough information that  
9 if there's a genuine dispute of material fact that I can't say  
10 as a matter of law loss causation does not apply to those  
11 disclosures.

12           What I'm going to do -- as I indicated, I will get an  
13 order out. The order will be very specific. I'm going to  
14 deny as to Curran, I'm going to grant as to Smith, I'm  
15 going to deny as to Martin, I'm going to deny the other  
16 portions as well.

17           If plaintiffs believe that there were other documents  
18 that they were relying on to show -- other SEC filings, I just  
19 don't have that before me. I'm not in a position to rule on  
20 those.

21           This case will be transferred from me tomorrow, and I  
22 will let the new judge know that there seemed to be a  
23 disagreement among the parties as to what other statements  
24 might be actionable in this case and that I did not rule on  
25 those.

1 MS. YADAVA: Your Honor, I'm very sorry to interrupt  
2 and keep Your Honor longer, but one question: Our brief has a  
3 whole section called AMF cannot establish defendants'  
4 liability for the statements not attributed to Smith or  
5 Martin, which are all of the corporate statements, and Your  
6 Honor just said that there's no corporate scienter. That's --  
7 all of those statements should be dismissed, as well, because  
8 there's no basis for liability from those statements without  
9 the doctrine of corporate scienter.

10 THE COURT: So they go forward on Martin and  
11 potentially on these Qs and K filings, I haven't had those,  
12 but if Martin is liable, I mean, in reality Celgene is  
13 going to be indemnifying him. Right?

14 MS. YADAVA: Your Honor, it's not about  
15 indemnification. It's about what statements remain in this  
16 case, and plaintiffs today threw up a whole bunch of 10Qs,  
17 10Ks in random statements. What our understandings now is  
18 that the class period on ozanimod would basically be from  
19 Martin's October statement, because that's his only statement,  
20 through the alleged corrective disclosure. But if Your Honor  
21 puts back in all of the corporate scienter statements, which  
22 Your Honor said this is not an instance in which corporate  
23 scienter should apply, it changes the parameters of  
24 Your Honor's decision.

25 THE COURT: That's a good question. I think actually

1 it's an evidential issue that is probably going to be  
2 extensively addressed in a motion in limine if this case goes,  
3 but I think you're right that once you get to that stage and  
4 then the trial judge is going to have to make a decision as to  
5 what plaintiffs can -- at least make a good-faith basis  
6 showing Martin knew or Martin did not know.

7           So that if Martin knew it or they can at least make a  
8 threshold showing that they can argue to the jury that Martin  
9 knew it, I think that would be admissible because it goes to  
10 his state of mind. If they can't make that threshold showing  
11 that Martin was aware of certain information, then I  
12 anticipate you're going to be granted the leave you seek now,  
13 which is they can't use that against Martin.

14           MS. YADAVA: Your Honor, I think I'm asking something  
15 differently. I'm not asking to use things against Martin.  
16 I'm just asking for Your Honor to include in his ruling that  
17 the corporate scienter statements are not actionable alleged  
18 misstatements because there is no corporate scienter, the  
19 doctrine doesn't apply.

20           So statements in the 10Ks and 10Qs and 8Ks earlier in  
21 the class period are no longer in this case because we moved  
22 on dismissal of the entirety of the ozanimod claims, including  
23 false statements not attributed to Smith or Martin. If  
24 plaintiffs thought there were statements that remained, they  
25 could have articulated those particular statements that they

1 articulated in argument today.

2 But, Your Honor, it changes the contours of the case a  
3 little bit and your ruling if we don't know whether the  
4 corporate scienter statements are in. My understanding is  
5 that's an issue of law as to whether the doctrine of --

6 THE COURT: You're right. It is an issue of law, but  
7 my problem with making that ruling is that I haven't ruled on  
8 the -- I don't know what their theory -- first of all, I don't  
9 know what the statements were. Second of all, I don't know  
10 what their theory of liability on any SEC filings are.

11 I will agree, as far as my rulings today, that  
12 corporate scienter does not apply, but I don't think -- I  
13 understand you've asked for it, but I have to be honest, I  
14 really didn't focus on any of the SEC filings. I just didn't  
15 read it as being an issue.

16 I don't want to hamstring plaintiffs at this point  
17 that if they think there's a Q or K statement that's still  
18 actionable as to who they think is liable for it. That I'm  
19 going to -- I can say I don't find that the doctrine of  
20 corporate scienter applies to the statements I'm ruling on.  
21 But I don't want to preclude them in case once they get  
22 those Qs and Ks, if they exist, that they say, "Well, this is  
23 who is responsible for them."

24 MS. YADAVA: Your Honor, the Qs and Ks are in the  
25 complaint, and pages 52 to 57 of our opening brief explain why



1 they're not actionable. They responded to it, Your Honor, and  
2 so did we in reply.

3 MR. ZIVITZ: Your Honor, if I may.

4 THE COURT: Yes.

5 MR. ZIVITZ: Your Honor, the Ks, the Qs, the 8Ks, as I  
6 mentioned earlier, they were corporate statements, they are  
7 Celgene statements. Our position is that there was scienter  
8 on behalf of Celgene in light of Defendant Martin having  
9 furnished information, having tolerated the misstatements, and  
10 also the ten other high-level managers that -- Maria  
11 Palmisano, Jay Backstrom, Terri Curran, all management-level  
12 folks who knew about the metabolite and knew about the risk.

13 What I would suggest, Your Honor, is Your Honor's point  
14 about the statements that Smith issued, the statements that  
15 Martin issued, your order is going to refer to those. To the  
16 extent -- you're right, whether or not it's motion in limine  
17 briefing, we can address it then as to the viability or the  
18 additional K and Q and corporate website statements that the  
19 company accepted. We can deal with that at a later point, but  
20 that is our position.

21 THE COURT: Right. What I read that issue to be -- I'm  
22 referring to pages 52, 53, 54 up to 55, the corporate  
23 scienter. What I had read that to be was more can Smith be  
24 liable if -- under *Janus*, before I even get to corporate  
25 scienter.

1           The question there was did Smith -- did he have the  
2           ultimate authority over certain information. I think the  
3           parties agree that ultimate authority over the statement would  
4           be sufficient.

5           I do apologize to counsel because I was not reading  
6           that in the context of any SEC filings. That wasn't how I  
7           read the argument. I think -- I know there's argument for  
8           corporate scienter, but I think both sides agree if somebody  
9           had ultimate authority over a filing and sign off that that  
10          person could be liable under *Janus*. I wasn't reading that  
11          argument in the context of any specific SEC filing.

12          MS. YADAVA: I think Your Honor just said, though, that  
13          you found that Smith didn't have scienter so his scienter  
14          cannot be imputed as the maker under *Janus*. Right?

15          THE COURT: Based on those statements, that's correct.  
16          But -- all I will say is if Smith signed off on a statement  
17          where they can now say he had the ultimate authority and  
18          it was material and misleading, that may be a different issue.  
19          I thought you said that Smith wasn't the one who filed the SEC  
20          filings.

21          MS. YADAVA: He didn't. That's the whole point,  
22          Your Honor. We point out in here these are attributed to  
23          other people. All of the SEC filings are attributed to other  
24          people, they are signed by other people, and the *Janus* case  
25          and others all say that if you have a filing that's attributed

1 to someone else, those people are the makers of the statement.

2 MR. ZIVITZ: Your Honor, if I may, these were all  
3 company statements. They are Celgene statements. They are  
4 not the -- just the signatory's statements. Otherwise  
5 companies could get off the hook and just point the finger at  
6 an unknowledgeable signatory.

7 So our position again is these are corporate statements  
8 and the scienter of ten-plus folks, including Martin, who  
9 Your Honor found at this stage there is a disputed issue of  
10 fact for the jury as to his scienter. All of that scienter  
11 goes to Celgene under any test, any *Cognizant* test. They  
12 furnished information and they tolerated the misrepresentation  
13 so all of those company statements, the Qs, the Ks, the 8Ks,  
14 and the corporate website slides, because Celgene accepted  
15 them, Martin's scienter and the other folks' scienter is  
16 imputed to Celgene for purposes of those statements.

17 MS. YADAVA: Your Honor, there's only two doctrines  
18 valid -- there are the only two doctrines addressing this, the  
19 only two doctrines addressed by plaintiffs. One is *Janus*.

20 Under *Janus*, if you have ultimate authority over a  
21 statement and you have scienter, your scienter can be imputed,  
22 you can be liable for those statements as the maker. We just  
23 found that Smith did not have scienter. He cannot be liable  
24 for those corporate statements that Mr. Zivitz just described.

25 The second doctrine is corporate scienter which only

1 applies, if it applies at all in the Third Circuit, to  
2 egregious circumstances when there's blatantly false  
3 statements. We don't have that here. Your Honor has already  
4 held that.

5         The two doctrines addressed in the briefing explain why  
6 we are entitled to the summary judgment on all of those  
7 additional statements. Your Honor's point that some of these  
8 are 10Ks and 10Qs and have other signatories only further  
9 bolsters this point, which is why summary judgment should be  
10 granted on all of this.

11         We moved in our papers on all statements relating to  
12 ozanimod, had detailed briefing on this, and we don't want  
13 Your Honor to, respectfully, say that those may still be in  
14 the case because under your rulings they should not be.

15         MR. ZIVITZ: Your Honor, if I may, just one more point  
16 on this.

17         Your Honor, we talked a lot about who knew what and  
18 when. The company, by virtue of all the people that worked on  
19 ozanimod, knew about the metabolite, knew about the risk no  
20 later than July, certainly knew about the risk by October.

21         If the company is issuing statements in 10Qs, 8Ks, and  
22 a 10K in January, those statements are actionable on behalf of  
23 the company by virtue of the folks who had scienter, which is  
24 Martin, Curran, Backstrom, Lamb, and others. Just because  
25 Smith is out doesn't mean that the scienter of the other

1 individuals isn't imputed to the company.

2 Ms. Yadava is not saying it but every case that she  
3 relies on is a pleading case. We're talking about evidence.  
4 Even under those cases, all three standards: the broad  
5 standard, the narrow standard, and the middle approach, which  
6 the middle approach and the broad standard is what the  
7 *Cognizant* court accepted at the pleading stage -- under those  
8 standards, if you furnish misinformation and you tolerate the  
9 misstatement, that scienter is imputed to the company.

10 That's exactly what we have here. To let Celgene get  
11 off the hook, that would turn corporate scienter on its head.

12 THE COURT: Let me just ask Ms. Yadava. I was focused  
13 on the individual statements, but what Mr. Zivitz is saying  
14 was in accord with my understanding of the law. If a company  
15 makes a filing, regardless of who signs it on behalf of the  
16 company, the company could be on the hook for it, if nothing  
17 else an adopted admission.

18 But I'm just trying to see what cases you have that say  
19 if the company makes a materially false statement or omission  
20 in an SEC filing they're not liable for it, only the person  
21 who signed off on it could be liable for it.

22 MS. YADAVA: Sure. Well, Your Honor, the only time  
23 there can be liability for corporate statements is if the  
24 signatory or the company as a whole had scienter. If you're  
25 deciding the company as a whole had scienter, that's the

1 corporate scienter doctrine that the Third Circuit has not  
2 adopted and that is supposed to be used in very rare context.

3 Mr. Zivitz is trying to explain this idea where we just  
4 take people's scienter and we put them all on the corporation.  
5 That is the doctrine of corporate scienter which the facts and  
6 circumstances do not present here such that corporate scienter  
7 should apply.

8 Your Honor has said this already on the record that  
9 corporate scienter does not apply in these instances. There's  
10 no blatantly false statements and there's no extraordinary  
11 circumstances or egregious culpable conduct, which is why  
12 there's no corporate scienter. There is no other theory other  
13 than the concept of *Janus*, which plaintiffs argue is basically  
14 taking Smith's scienter and imposing it on the company and  
15 making him the maker of those statements, but we just  
16 determined that Smith doesn't have scienter, so there's no  
17 scienter of Smith to impute on the company and he didn't have  
18 ultimate authority so he couldn't have anyway.

19 Even putting aside the ultimate authority point, that  
20 point only works if Smith had scienter to impute to the  
21 company.

22 THE COURT: The reason I said the corporate scienter  
23 doctrine doesn't apply, besides the fact the Third Circuit  
24 hasn't expressly adopted it, is because you need egregious  
25 behavior.

1 MS. YADAVA: Yeah.

2 THE COURT: To me, under plaintiffs' best case this  
3 wasn't that type of behavior. This was disclosing a potential  
4 risk that was known to Martin or at least potentially known to  
5 Martin -- that's going to be for a jury to decide -- and  
6 others that Martin interacted with. That will come down to  
7 what Martin knew, when he knew it, and then what his reaction  
8 was and whether the jury finds him credible or not.

9 As to the Qs and Ks, I have not -- I just haven't  
10 focused on that issue. I don't want to make a ruling now  
11 without having gone through to say who could be liable and Qs  
12 and Ks and so forth. My understanding was, if the company  
13 makes a materially false statement or omission and there's  
14 scienter and there's loss causation and so forth, there could  
15 be potential liability for the company.

16 But I think what you're saying, Ms. Yadava, is if  
17 somebody drafts it and they have bad scienter but they don't  
18 have the ultimate authority and then somebody else who has the  
19 ultimate authority signs off on it not knowing that this is  
20 intentionally false or a misstatement, that there's no  
21 liability in that case.

22 MR. ZIVITZ: Your Honor if I may, can I just add one  
23 thing?

24 THE COURT: Sure.

25 MR. ZIVITZ: The cases that Ms. Yadava keeps bringing

1 up in terms of saying it has to be egregious, those again are  
2 pleading-stage cases. What the court held there in *Cognizant*  
3 is we look at egregious situations in order to draw the  
4 inference that the company is responsible because we don't  
5 have the individuals -- we don't have evidence of the  
6 individuals at issue.

7           Here we have that evidence. We have hard evidence that  
8 upper management knew about the metabolite and knew about the  
9 risk. That's why I keep saying those pleading cases are  
10 inapposite. But, again, even if they apply here -- let's just  
11 say that *Cognizant* applies. Under all of those standards what  
12 the court held, what Judge Walls held, what Judge Salas held,  
13 is if a bad actor, someone with scienter, furnishes  
14 information to the corporate entity, which is exactly  
15 what Martin and the NDA folks did, or tolerates the  
16 misrepresentation after it's uttered, that scienter gets  
17 imputed to the company under the pleading standard.

18           Here, again, we are at the evidentiary standard and we  
19 have scores of evidence showing that Martin, Jay Backstrom,  
20 Palmisano, Gondi Kumar, the entire company knew about the NDA.  
21 The idea that somehow because it's not akin to criminal  
22 conduct that somehow the company gets off the hook for being  
23 responsible for its statements, that is not at all what the  
24 securities law are meant to guard against. Here you have the  
25 folks who give the information --



1 THE COURT: I'm going to reserve on this particular  
2 issue, but when I issue the order, I'm going to do an addendum  
3 opinion as to this particular issue. Okay.

4 MR. ZIVITZ: Thank you, Your Honor.

5 THE COURT: I think it's only fair. I understood the  
6 argument differently from defendants. I'm not saying that --  
7 and what Ms. Yadava is saying right now makes sense. That is  
8 not the way I read the motion papers.

9 Let me reserve on the issue, and I'll just do a short  
10 addendum as to this particular issue under both *Janus* and  
11 corporate scienter and who it could be attributable to. Okay.

12 MR. ZIVITZ: Thank you, Your Honor.

13 THE COURT: I think that's the only fair thing at this  
14 point. I have to take a look at the issue.

15 MS. YADAVA: Understood, Your Honor. Thank you.

16 MR. ZIVITZ: We appreciate it.

17 THE COURT: Thank you, counsel.

18 Mr. Cecchi, go ahead.

19 MR. CECCHI: Judge, I think I would be committing an  
20 omission if I didn't say, since this will be the last time we  
21 appear before Your Honor, that we certainly appreciate the  
22 hard work you did not on this case but in the many years you  
23 have been on the bench.

24 The Bar is going to miss you, I know your colleagues  
25 are going to miss you, but we all wish you the best in the

1 exciting new ventures for you and your family and we will see  
2 you again.

3 THE COURT: Thank you, Mr. Cecchi.

4 Mr. Cecchi is being remiss because I'm going to work  
5 with him on Monday. No, I'm only kidding. I'm not going to  
6 work with Mr. Cecchi on Monday or Mr. Lustberg.

7 MR. LUSTBERG: Actually, coincidentally I'm going to a  
8 meeting at what will be your new firm in a few minutes.

9 THE COURT: Tell them I said "hello."

10 MR. LUSTBERG: Good luck, John.

11 THE COURT: Thank you, all.

12 (Which were all the proceedings held  
13 in the above-entitled matter on said date.)

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**FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE**

I, **Lisa A. Larsen**, RPR, RMR, CRR, FCRR, Official Court Reporter of the United States District Court for the District of New Jersey, do hereby certify that the foregoing proceedings are a true and accurate transcript from the record of proceedings in the above-entitled matter.

/S/Lisa A. Larsen, RPR, RMR, CRR, FCRR

Official U.S. District Court Reporter ~

District of New Jersey

DATED this September 11, 2023

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